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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. USCBP–2021–0050]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security U.S. Customs and Border Protection–014 Regulatory Audit Archive System (RAAS) System of Records

AGENCY: U.S. Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: Final rule.

SUMMARY: The U.S. Department of Homeland Security (DHS) is issuing a final rule to extend the exemptions from certain provisions of the Privacy Act to the updated and reissued system of records titled, ''DHS/U.S. Customs and Border Protection–014 Regulatory Audit Archive System (RAAS) System of Records.'' Specifically, the Department exempts portions of this system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: This final rule is effective February 4, 2022.

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Debra Danisek, *Privacy.CBP@cbp.dhs.gov,* (202) 344–1610, CBP Privacy Officer, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Washington, DC 20229. For privacy issues please contact: Lynn Parker Dupree, *Privacy@hq.dhs.gov,* (202–343–1717), Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Department of Homeland Security (DHS) U.S. Customs and Border Protection (CBP) published a notice of proposed rulemaking in the **Federal Register**, 81 FR 19932, April 6, 2016, proposing to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements. DHS reissued the ''DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records'' in the **Federal Register** at 81 FR 19985, April 6, 2016, to provide notice to the public that DHS/CBP was updating the categories of records to include the capture of Employer Identification Numbers (EIN) or Social Security numbers (SSN), also known as a Federal Taxpayer Identifying Number, pursuant to 19 CFR 24.5, 19 CFR 149.3, and Executive Order 9397, as amended by Executive Order 13748.

DHS is revising the previously claimed exemptions from certain requirements of the Privacy Act for DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records. DHS/CBP is not requesting an exemption with respect to information maintained in the system as it relates to data submitted by or on behalf of a subject of an audit. The Privacy Act requires DHS to maintain an accounting of the disclosures made pursuant to all routines uses. Disclosing the fact that a law enforcement or intelligence agency has sought particular records may affect ongoing law enforcement activity. Therefore, pursuant to 5 U.S.C. 552a(k)(2), DHS will claim exemption from section (c)(3) of the Privacy Act of 1974, as amended, as is necessary and appropriate to protect this information.

Some information in DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records relates to official DHS law enforcement activities. These exemptions are needed to protect information relating to DHS law enforcement activities from disclosure to subjects or others related to these activities. Specifically, the exemptions are required to preclude subjects of these activities from frustrating these processes; to avoid disclosure of activity techniques; to protect the identities and physical safety of confidential informants and law enforcement personnel; to ensure DHS's ability to obtain information from third parties and other sources; to protect the privacy of third parties; and to safeguard classified information. Disclosure of information to the subject of the inquiry could also permit the subject to avoid detection or apprehension.

The exemption proposed here is a standard law enforcement exemption exercised by a large number of federal law enforcement agencies. In appropriate circumstances, where compliance would not appear to interfere with or adversely affect the law enforcement purposes of this system and the overall law enforcement process, the applicable exemptions may be waived on a case-by-case basis.

DHS/CBP invited comments on both the Notice of Proposed Rulemaking (NPRM) and System of Records Notice (SORN).

II. Public Comments

DHS received no comments on the NPRM or the SORN and will implement the rulemaking as proposed.

List of Subjects in 6 CFR Part 5

Freedom of information, Privacy.

For the reasons stated in the preamble, DHS amends chapter I of title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

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

Authority: 6 U.S.C. 101 *et seq.*; Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. In appendix C to part 5, revise section 25 to read as follows:

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

25. The U.S. Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP)–014 Regulatory Audit Archive System (RAAS) System of Records consists of electronic and paper records and will be used by DHS and its Components. The DHS/CBP–014 RAAS System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, but not limited to, the enforcement of civil and criminal laws, and investigations, inquiries, and proceedings there under.

The DHS/CBP–014 RAAS System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its Components and may contain personally identifiable information collected by other federal, state, local, tribal, foreign, or international government agencies. The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3). Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) [Reserved]

* * * * *

Lynn P. Dupree,

Chief Privacy Officer, U.S. Department of Homeland Security.

[FR Doc. 2022–02004 Filed 2–3–22; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0088; Project Identifier AD–2022–00041–A; Amendment 39–21941; AD 2022–03–23]

RIN 2120–AA64

Airworthiness Directives; Textron Aviation Inc. (Type Certificate Previously Held by Raytheon Aircraft Company, Hawker Beechcraft Corporation, and Beechcraft Corporation) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Textron Aviation Inc. (type certificate previously held by Raytheon Aircraft Company, Hawker Beechcraft Corporation, and Beechcraft Corporation) (Textron) Model 300, 300LW, B300, and B300C airplanes. This AD was prompted by a report of a timing issue where the yaw servo software can generate a motor position fault when the pilot applies rudder input at the same time the rudder boost system is activated, which disables the rudder boost function and leads to a reduced ability of the flight crew to maintain the safe flight and landing of the airplane or loss of control of the airplane. This AD requires updating the software version of the yaw servo. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 22, 2022.

The FAA must receive comments on this AD by March 21, 2022.

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

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

For service information identified in this final rule, contact Garmin International, Garmin Aviation Support, 1200 E 151st Street, Olathe, KS 66062; phone: (866) 739–5687; website: *https://fly.garmin.com/fly-garmin/support/.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust St., Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0088; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Phil Petty, Aviation Safety Engineer, Wichita ACO Branch, FAA, 1801 Airport Road, Wichita, KS 67209; phone: (316) 946–4139; email: *philip.petty@faa.gov* or *Wichita-COS@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Garmin informed the FAA of a problem during flight testing with the Garmin International, Inc., G1000 integrated avionics system installed on Textron Model 300, 300LW, B300, and B300C airplanes in accordance with Supplemental Type Certificate (STC) No. SA01535WI–D. A timing issue in the yaw servo software can generate a motor position fault when the pilot applies rudder input at the same time the rudder boost system is activated, which disables the rudder boost function.

The rudder boost system applies additional rudder force, using the GSA 9000 yaw servo, following loss of an engine or significant loss of thrust, which limits the rudder force required to maintain directional control of the airplane. Loss of the rudder boost system without warning before the moment rudder boost is needed could result in the inability of the flight crew to maintain the safe flight and landing of the airplane or loss of control of the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information

The FAA reviewed Garmin STC Service Bulletin No. 21120, Revision A, dated December 10, 2021. This service information specifies updating the software version of the GSA 9000 yaw servo to version 2.14.

The FAA also reviewed Garmin Service Alert No. 21119, Revision A, dated November 18, 2021; and Garmin Service Alert No. 21119, Revision B, dated December 10, 2021. Revision A of this service information advises owners and operators of the unsafe condition previously described, while Revision B identifies the resolution by complying with Garmin STC Service Bulletin No. 21120, Revision A, dated December 10, 2021.

AD Requirements

This AD requires updating the GSA 9000 yaw servo software to a version that is not 2.13 or earlier.

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

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because loss of rudder boost following an engine loss or significant loss of thrust is likely to occur. This could result in the inability of the flight crew to maintain the safe flight and landing of the airplane and loss of control of the airplane. Many of the affected airplanes operate more than 800 flight hours annually. Because of the nature of the unsafe condition and the utilization rate of these airplanes, the corrective actions to mitigate this unsafe condition must be done within 100 flight hours or 3 months, whichever occurs first after the effective date of this AD. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest 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.

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–2022–0088 and Project Identifier AD–2022–00041–A'' 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 *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this 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 Phil Petty, Aviation Safety Engineer, Wichita ACO Branch, FAA, 1801 Airport Road, Wichita, KS 67209. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

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

The FAA estimates that this AD affects 300 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 airplane	Cost on U.S. operators
Update yaw servo software	1 work-hour × $85 per hour = $85	Not Applicable	$85	$25,500

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, and

(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 adding the following new airworthiness directive:

2022–03–23 Textron Aviation Inc. (type certificate previously held by Raytheon Aircraft Company, Hawker Beechcraft Corporation, and Beechcraft Corporation): Amendment 39–21941; Docket No. FAA–2022–0088; Project Identifier AD–2022–00041–A.

(a) Effective Date

This airworthiness directive (AD) is effective February 22, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Textron Aviation Inc. (type certificate previously held by Raytheon Aircraft Company, Hawker Beechcraft Corporation, and Beechcraft Corporation) Model 300, 300LW, B300, and B300C airplanes, all serial numbers, certificated in any category, that are equipped with a Garmin International, Inc., G1000 integrated avionics system installed in accordance with Supplemental Type Certificate No. SA01535WI–D with GSA 9000 yaw servo software version 2.13 or earlier.

(d) Subject

Joint Aircraft System Component (JASC) Code 2720, Rudder Control System.

(e) Unsafe Condition

This AD was prompted by a report of a timing issue where the yaw servo software can generate a motor position fault when the pilot applies rudder input at the same time the rudder boost system is activated, which disables the rudder boost. The FAA is issuing this AD to prevent excessive rudder forces following loss of an engine or significant loss of thrust. The unsafe condition, if not addressed, could result in the inability of the flight crew to maintain the safe flight and landing of the airplane and loss of control of the airplane.

(f) Actions and Compliance

(1) Unless already done, within 100 hours time-in-service (TIS) after the effective date of this AD or within 90 days after the effective date of this AD, whichever occurs first, update the GSA 9000 yaw servo software to a version that is not 2.13 or earlier.

(2) As of the effective date of this AD, do not install yaw servo software version 2.13 or earlier on the Garmin G1000 integrated avionics system on any airplane.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita 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 (h) of this AD.

(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.

(h) Related Information

For more information about this AD, contact Phil Petty, Aviation Safety Engineer, Wichita ACO Branch, FAA, 1801 Airport Road, Wichita, KS 67209; phone: (316) 946–4139; email: *philip.petty@faa.gov* or *Wichita-COS@faa.gov*.

(i) Material Incorporated by Reference

None.

Issued on February 1, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–02398 Filed 2–1–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0980; Airspace Docket No. 21–AGL–32]

RIN 2120–AA66

Amendment of Class D and Class E Airspace; Janesville, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D and Class E airspace at Janesville, WI. This action is the result of an airspace review caused by the decommissioning of the Rockford very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The names and geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, May 19, 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 JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace and Class E airspace extending upward from 700 feet above the surface at Southern Wisconsin Regional Airport, Janesville, WI, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal**

Register (86 FR 62755; November 12, 2021) for Docket No. FAA–2021–0980 to amend the Class D and Class E airspace at Janesville, WI. 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 D and E airspace designations are published in paragraphs 5000 and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and 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 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71:

Amends the Class D airspace to within a 4.3-mile (increased from a 4.1-mile) radius of Southern Wisconsin Regional Airport, Janesville, WI; adds an extension 1 mile each side of the 221° bearing from the airport extending from the 4.3-mile radius of the airport to 4.4 miles southwest of the airport; adds an extension 1 mile each side of the 331° bearing from the airport extending from the 4.3-mile radius of the airport to 4.4 miles northwest of the airport; updates the name (previously Rock County Airport) and geographic coordinates of the airport to coincide with the FAA's aeronautical database; removes 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 updates the outdated term ''Airport/Facility Directory'' to ''Chart Supplement'';

And amends the Class E airspace extending upward from 700 feet above the surface to within a 6.8-mile (decreased from an 8.9-mile) radius of Southern Wisconsin Regional Airport; adds an extension 2 miles each side of the 042° bearing from the airport extending from the 6.8-mile radius of the airport to 10.9 miles northeast of the airport; removes the city associated with the airport from the airspace legal description to comply with changes to FAA Order JO 7400.2N; and removes the exclusionary language as it is not required.

This action is due to an airspace review caused by the decommissioning of the Rockford VOR, which provided navigation information for the instrument procedures this airport, as part of the VOR MON Program.

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 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL WI D Janesville, WI [Amended]

Southern Wisconsin Regional Airport, WI
(Lat. 42°37′13″ N, long. 89°02′30″ W)

That airspace extending from the surface to and including 3,300 feet MSL within a 4.3-mile radius of the Southern Wisconsin Regional Airport, and within 1 mile each side of the 221° bearing from the airport extending from the 4.3-mile radius of the airport to 4.4 miles southwest of the airport, and within 1 mile each side of the 331° bearing from the airport extending from the 4.3-mile radius of the airport to 4.4 miles northwest of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

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

* * * * *

AGL WI E5 Janesville, WI [Amended]

Southern Wisconsin Regional Airport, WI
(Lat. 42°37′13″ N, long. 89°02′30″ W)
Beloit Airport, WI
(Lat. 42°29′52″ N, long. 88°58′03″ W)

That airspace extending upward from 700 feet above the surface within an 6.8-mile radius of the Southern Wisconsin Regional Airport, and within 2 miles each side of the 042° bearing from the Southern Wisconsin Regional Airport extending from the 6.8-mile radius of the Southern Wisconsin Regional Airport to 10.9 miles northeast of the Southern Wisconsin Regional Airport, and within a 6.3-mile radius of the Beloit Airport.

Issued in Fort Worth, Texas, on January 31, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–02277 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0976; Airspace Docket No. 21–ASW–22]

RIN 2120–AA66

Revocation of Class E Airspace; Carrizo Springs, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes the Class E airspace at Glass Ranch Airport, Carrizo Spring, TX. This action is the result of the cancellation of the instrument procedures and closure of the airport. The geographic coordinates of the Indio-Faith Airport, Carrizo Spring, TX, are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, May 19, 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 JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it revokes the Class E airspace extending upward from 700 feet above the surface at Glass Ranch Airport, Carrizo Springs, TX, due to the cancellation of the instrument procedures and closure of the airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 62760; November 12, 2021) for Docket No. FAA–2021–0976 to amend the Class E airspace at Glass Ranch Airport, Carrizo Spring, TX. 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 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 removes Glass Ranch Airport, Carrizo Spring, TX, and the associated airspace from the airspace legal description; updates the header to ''Carrizo Springs, TX'' (previously Carrizo Springs, Glass Ranch Airport, TX) to coincide with the FAA's aeronautical database; removes the city associated with the airports in the airspace legal description to comply with changes to FAA Order JO 7400.2N, Procedures for Handling Airspace Matters; and updates the geographic coordinates of Indio-Faith Airport, Carrizo Springs, TX, to coincide with the FAA's aeronautical database.

This action is necessary due to the cancellation of the instrument procedures and closure of the Glass Ranch Airport.

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 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ASW TX E5 Carrizo Springs, TX [Amended]

Indio-Faith Airport, TX
(Lat. 28°15′48″ N, long. 100°09′46″ W)
Faith Ranch Airport, TX
(Lat. 28°12′31″ N, long. 100°01′08″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Indio-Faith Airport, and within a 6.4-mile radius of Faith Ranch Airport, excluding that airspace within Mexico.

Issued in Fort Worth, Texas, on January 31, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–02271 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0978; Airspace Docket No. 21–ASW–21]

RIN 2120–AA66

Amendment of the Class D and Class E Airspace and Revocation of Class E Airspace; Hammond, LA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D and Class E airspace and revokes Class E airspace at Hammond, LA. This action is the result of an airspace review due to the decommissioning of the Hammond very high frequency (VHF) omnidirectional range (VOR).

DATES: Effective 0901 UTC, May 19, 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 JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace and the Class E airspace extending upward from 700 feet above the surface, and removes the Class E airspace area designated as an extension to the Class D airspace at Hammond Northshore Regional Airport, Hammond, LA, to support instrument flight rule operations at this airport, and removes the Class E airspace area designated as an extension to the Class D airspace at Hammond Municipal Airport, Hammond, LA, as it is duplicate airspace.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 62749; November 12, 2021) for Docket No. FAA–2021–0978 to amend the Class D and Class E airspace and revoke Class E airspace at Hammond, LA. 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 D and E airspace designations are published in paragraphs 5000, 6004, and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and 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 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71:

Amends the Class D airspace at Hammond Northshore Regional Airport, Hammond, LA, by replacing the outdated term ''Airport/Facility Directory'' with ''Chart Supplement;''

Removes the Class E airspace area designated as an extension to the Class D airspace at Hammond Northshore Regional Airport as it is no longer required;

Removes the Class E airspace extending upward from 700 feet above the surface at Hammond Municipal Airport, Hammond, LA, as it is duplicate airspace and not required;

And amends the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (decreased from a 7.5-mile) radius of Hammond Northshore Regional Airport.

This action is the result of an airspace review due to the decommissioning of the Hammond VOR which provided guidance to instrument procedures at this airport.

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 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASW LA D Hammond, LA [Amended]

Hammond Northshore Regional Airport, LA
(Lat. 30°31′18″ N, long. 90°25′06″ W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.1-mile radius of Hammond Northshore Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. 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.

* * * * *

ASW LA E4 Hammond, LA [Removed]

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

* * * * *

ASW LA E5 Hammond, LA [Removed]

ASW LA E5 Hammond, LA [Amended]

Hammond Northshore Regional Airport, LA
(Lat. 30°31′18″ N, long. 90°25′06″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Hammond Northshore Regional Airport.

Issued in Fort Worth, Texas, on January 31, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–02269 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0979; Airspace Docket No. 21–AGL–31]

RIN 2120–AA66

Amendment of Class D and Class E Airspace; Multiple Illinois Towns

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D airspace at Chicago/Rockford, IL, and the Class E airspace at Poplar Grove, IL; Freeport, IL; Rochelle, IL; and Chicago/Rockford, IL. This action is the result of airspace reviews caused by the decommissioning of the Rockford very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The names and geographic coordinates of various airports are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, May 19, 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 JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace at Chicago/Rockford International Airport, Chicago/Rockford, IL, and the Class E airspace extending upward from 700 feet above the surface at Poplar Grove Airport, Poplar Grove, IL; Albertus Airport, Freeport, IL; Rochelle Municipal Airport/Koritz Field, Rochelle, IL; and Chicago/Rockford International Airport to support instrument flight rule operations at these airports.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 62753; November 12, 2021) for Docket No. FAA–2021–0979 to amend the Class D airspace at Chicago/Rockford, IL, and the Class E airspace at Poplar Grove, IL; Freeport, IL; Rochelle, IL; and Chicago/Rockford, IL. 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 D and E airspace designations are published in paragraphs 5000 and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR

71.1. The Class D and 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 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Subsequent to publication of the NPRM it was discovered that the proposed southwest extension referencing the Chicago/Rockford INTL: RWY 07–LOC to the Class D airspace at Chicago/Rockford International Airport is already contained within the Class D radius and is not required. That proposed extension has been removed in this action.

The Rule

This amendment to 14 CFR part 71:

Amends the Class D airspace at Chicago/Rockford International Airport, Chicago/Rockford, IL, by adding an extension 1 mile each side of the 185° bearing from the airport extending from the 4.6-mile radius of the airport to 4.7 miles south of the airport; and updates the header of the airspace legal description from ''Rockford, IL'' to ''Chicago/Rockford, IL'' to coincide with the FAA's aeronautical database;

Amends the Class E airspace extending upward from 700 feet above the surface at Poplar Grove Airport, Poplar Grove, IL, by updating the name of the airport (previously Belvidere LTD Airport) to coincide with the FAA's aeronautical database; updates the header of the airspace legal description from ''Belvidere, IL'' to ''Poplar Grove, IL'' to coincide with the FAA's aeronautical database; and removes the exclusionary language as it is not required;

Amends the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (increased from a 6.5-mile) radius of Albertus Airport, Freeport, IL; removes 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 updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Amends the Class E airspace extending upward from 700 feet above the surface at Rochelle Municipal Airport/Koritz Field, Rochelle, IL, by updating the name (previously Airport-Koritz Field) and geographic coordinates of the airport to coincided with the FAA's aeronautical database; and removes the exclusionary language as it is not required;

And amends the Class E airspace extending upward from 700 feet above the surface at Chicago/Rockford International Airport by adding an extension within 3 miles each side of the 185° bearing of the Chicago/Rockford INTL: RWY 01–LOC extending from the 7.1-mile radius of the airport to 12.3 miles south of the Chicago/Rockford INTL: RWY 01–LOC; and updates the header of the airspace legal description from ''Rockford, IL'' to ''Chicago/Rockford, IL'' to coincide with the FAA's aeronautical database.

This action is due to airspace reviews caused by the decommissioning of the Rockford VOR, which provided navigation information for the instrument procedures these airports, as part of the VOR MON Program.

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 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL IL D Chicago/Rockford, IL [Amended]

Chicago/Rockford International Airport, IL
(Lat. 42°11′43″ N, long. 89°05′50″ W)

That airspace extending upward from the surface of the earth to and including 3,200 feet MSL within a 4.6-mile radius of the Chicago/Rockford International Airport, and within 1 mile each side of the 185° bearing from the airport extending from the 4.6-mile radius of the airport to 4.7 miles south of the airport.

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

* * * * *

AGL IL E5 Poplar Grove, IL [Amended]

Poplar Grove Airport, IL
(Lat. 42°19′22″ N, long. 88°50′11″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Poplar Grove Airport.

* * * * *

AGL IL E5 Freeport, IL [Amended]

Albertus Airport, IL
(Lat. 42°14′46″ N, long. 89°34′55″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Albertus Airport.

* * * * *

AGL IL E5 Rochelle, IL [Amended]

Rochelle Municipal Airport/Koritz Field, IL
(Lat. 41°53′34″ N, long. 89°04′47″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Rochelle Municipal Airport/Koritz Field.

AGL IL E5 Chicago/Rockford, IL [Amended]

Chicago/Rockford International Airport, IL
(Lat. 42°11′43″ N, long. 89°05′50″ W)
Chicago/Rockford INTL: RWY 01–LOC
(Lat. 42°12′36″ N, long. 89°05′17″ W)

That airspace extending upward from 700 feet above the surface within a 7.1-mile radius of the Chicago/Rockford International Airport, and within 3 miles each side of the 185° bearing from the Chicago/Rockford INTL: RWY 01–LOC extending from the 7.1-mile radius of the airport to 12.3 miles south of the Chicago/Rockford INTL: RWY 01–LOC.

Issued in Fort Worth, Texas, on January 31, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–02270 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0977; Airspace Docket No. 21–ASW–20]

RIN 2120–AA66

Amendment Class E Airspace; Hugo, OK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Hugo, OK. This action is the result of an airspace review due to the decommissioning of the Hugo non-directional beacon (NDB). The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, May 19, 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 JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Stan Stamper Municipal Airport, Hugo, OK, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 62758; November 12, 2021) for Docket No. FAA–2021–0977 to amend the Class E airspace at Hugo, OK. 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 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Subsequent to publication a typographic error was discovered in the geographic coordinates published in the airspace legal description, ''(lat. 34°02′06″ N, long. 95°32′31″ W)'' vice ''(lat. 34°02′01″ N, long. 95°32′31″ W)''. That error has been corrected in this action.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface to within a 6.4-mile (increased from a 6.3-mile) radius of Stan Stamper Municipal Airport, Hugo, OK; removes the Hugo NDB and associated extension from the airspace legal description; updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and removes the exclusionary language as it is not required.

This action is the result of an airspace review due to the decommissioning of the Hugo NDB which provided guidance to instrument procedures at this airport.

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 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ASW OK E5 Hugo, OK [Amended]

Stan Stamper Municipal Airport, OK
(Lat. 34°02′01″ N, long. 95°32′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Stan Stamper Municipal Airport.

Issued in Fort Worth, Texas, on January 31, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–02272 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0814; Airspace Docket No. 21–AGL–30]

RIN 2120–AA66

Amendment of Class D and Class E Airspace and Revocation of Class E Airspace; Rochester and St. Cloud, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D and Class E airspace at Rochester International Airport, Rochester, MN, and St. Cloud Regional Airport, St. Cloud, MN, and revokes the Class E airspace at Rochester International Airport. This action is the result of biennial airspace reviews. The geographic coordinates of St. Cloud Regional Airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, May 19, 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 JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace, the Class E surface airspace, and the Class E airspace extending upward from 700 feet above the surface at Rochester International Airport, Rochester, MN; revokes the Class E airspace designated as an extension to Class D and Class E surface areas at Rochester International Airport; amends the Class D airspace, the Class E surface area, the Class E airspace designated as an extension to Class D and Class E surface areas, and the Class E airspace extending upward from 700 feet above the surface at St. Cloud Regional Airport, St. Cloud, MN, to support instrument flight rule operations at these airports.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 62750; November 12, 2021) for Docket No. FAA–2021–0814 to amend the Class D and Class E airspace at Rochester International Airport, Rochester, MN, and St. Cloud Regional Airport, St. Cloud, MN, and revoke Class E airspace at Rochester International Airport. 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 D and E airspace designations are published in paragraphs 5000, 6002, 6004, and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and 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 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E

airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Subsequent to publication of the NPRM, the FAA discovered a typographic error in the St. Cloud, MN, Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area airspace legal description. The radius of the airport should be ''4.2-mile'' vice '4.4-mile.'' As this change does not affect the Class E airspace area as proposed, it is incorporated into this rule.

The Rule

This amendment to 14 CFR part 71:

Amends the Class D airspace to within a 4.4-mile (increased from a 4.3-mile) radius of Rochester International Airport, Rochester, MN; removes the Rochester VOR/DME from the airspace legal description as it is not required; and updates the outdated term ''Airport/Facility Directory'' to ''Chart Supplement'';

Amends the Class D airspace to within a 4.2-mile (increased from a 4.1-mile) radius of St. Cloud Regional Airport, St. Cloud, MN; updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and updates the outdated term ''Airport/Facility Directory'' to ''Chart Supplement'';

Amends the Class E surface area to within a 4.4-mile (increased from a 4.3-mile) radius of Rochester International Airport; removes the Rochester VOR/DME and associated extension from the airspace legal description as they are no longer required; and updates the outdated term ''Airport/Facility Directory'' to ''Chart Supplement'';

Amends the Class E surface area to within a 4.2-mile (increased from a 4.1-mile) radius of St. Cloud Regional Airport; removes the St. Cloud VOR/DME and associated extension from the airspace legal description as they no longer required; updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and updates the outdated term ''Airport/Facility Directory'' to ''Chart Supplement'';

Removes the Class E airspace designated as an extension to Class D and Class E surface areas at Rochester International Airport as it is no longer required;

Amends the Class E airspace designated as an extension to Class D and Class E surface areas at St. Cloud Regional Airport to within 2.4 miles each side of the St. Cloud VOR/DME 140° (previously 143°) radial extending from the 4.2-mile (increased from 4.1-mile) radius of the St. Cloud Regional Airport to 7 (decreased from 7.2) miles southeast of the St. Cloud VOR/DME (previously airport); and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Amends the Class E airspace extending upward from 700 feet above the surface to within a 6.9-mile (increased from a 6.8-mile) radius of Rochester International Airport; removes the Rochester VOR/DME and associated extension from the airspace legal description as they are no longer required; adds an extension within 2 miles each side of the 132° bearing from the airport extending from the 6.9-mile radius to 10.9 miles southeast of the airport; amends the southeast extension to within 4 miles each side of the 132° bearing from the Rochester Intl.: RWY 31–LOC (previously 5.3 miles northeast and 4 miles southwest of the Rochester southeast localizer course) extending from the 6.9-mile (increased from a 6.8-mile) radius to 7.5 miles (decreased from 17.3 miles) southeast of the airport; amends the northwest extension to within 3.9 miles each side of the 312° bearing from the Rochester Intl.: RWY 13–LOC (previously 5.3 miles southwest and 4 miles northeast of the Rochester northwest localizer course) extending from the 6.9-mile (increased from 6.8-mile) radius of the airport to 11.4 (decreased from 20) miles northwest of the airport;

And amends the Class E airspace extending upward from 700 feet above the surface to within a 6.7-mile (increased from 6.6-mile) radius of St. Cloud Regional Airport; amends the southeast extension to within 2.4 miles each side of the St. Cloud VOR/DME 140° (previously 143°) radial extending from the 6.7-mile (increased from 6.6-mile) radius of the airport to 7 (decrease from 7.2) miles southeast of the St. Cloud VOR/DME (previously airport); and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to biennial airspace reviews.

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 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL MN D Rochester, MN [Amended]

Rochester International Airport, MN
(Lat. 43°54′30″ N, long. 92°30′00″ W)

That airspace extending upward from the surface to and including 3,800 feet MSL within a 4.4-mile radius of the Rochester International Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will

thereafter be published continuously in the Chart Supplement.

AGL MN D St. Cloud, MN [Amended]

St. Cloud Regional Airport, MN
(Lat. 45°32′46″ N, long. 94°03′34″ W)

That airspace extending upward from the surface to and including 3,500 feet MSL within a 4.2-mile radius of the St. Cloud Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Designated as a Surface Area.

* * * * *

AGL MN E2 Rochester, MN [Amended]

Rochester International Airport, MN
(Lat. 43°54′30″ N, long. 92°30′00″ W)

Within a 4.4-mile radius of Rochester International Airport. This Class E airspace area is effective during the specific dates and times established by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

AGL MN E2 St. Cloud, MN [Amended]

St. Cloud Regional Airport, MN
(Lat. 45°32′46″ N, long. 94°03′34″ W)

Within a 4.2-mile radius of St. Cloud Regional Airport. This Class E airspace area is effective during the specific dates and times established by a Notice to Airmen. 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 MN E4 Rochester, MN [Removed]

AGL MN E4 St. Cloud, MN [Amended]

St. Cloud Regional Airport, MN
(Lat. 45°32′46″ N, long. 94°03′34″ W)
St. Cloud VOR/DME
(Lat. 45°32′58″ N, long. 94°03′31″ W)

That airspace extending upward from the surface within 2.4 miles each side of St. Cloud VOR/DME 140° radial extending from the 4.2-mile radius of St. Cloud Regional Airport to 7 miles southeast of the St. Cloud VOR/DME.

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

* * * * *

AGL MN E5 Rochester, MN [Amended]

Rochester International Airport, MN
(Lat. 43°54′30″ N, long. 92°30′00″ W)
Rochester Intl.: RWY 31–LOC
(Lat. 43°55′19″ N, long. 92°30′54″ W)
Rochester Intl.: RWY 13–LOC
(Lat. 43°54′06″ N, long. 92°29′02″ W)
Mayo Clinic-St. Mary's Hospital, MN
(Lat. 44°01′11″ N, long. 92°28′59″ W)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of the Rochester International Airport, and within 2 miles each side of the 132° bearing from the Rochester International Airport extending from the 6.9-mile radius of Rochester International Airport to 10.9 miles southeast of Rochester International Airport, and within 4 miles each side of the 132° bearing from the Rochester Intl.: RWY 31–LOC extending from the 6.9-mile radius of Rochester International Airport to 7.5 miles southeast of Rochester International Airport, and within 3.9 miles each side of the 312° bearing from the Rochester Intl.: RWY 13–LOC extending from the 6.9-mile radius of Rochester International Airport to 11.4 miles northwest of Rochester International Airport, and within a 6.4-mile radius of the Mayo Clinic-St. Mary's Hospital.

* * * * *

AGL MN E5 St. Cloud, MN [Amended]

St. Cloud Regional Airport, MN
(Lat. 45°32′46″ N, long. 94°03′34″ W)
St. Cloud VOR/DME
(Lat. 45°32′58″ N, long. 94°03′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of St. Cloud Regional Airport, and within 2.4 miles each side of the St. Cloud VOR/DME 140° extending from the 6.7-mile radius of the airport to 7 miles southeast of the St. Cloud VOR/DME.

Issued in Fort Worth, Texas, on January 31, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–02276 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2021–N–0807]

Medical Devices; Immunology and Microbiology Devices; Classification of the System for Detection of Microorganisms and Antimicrobial Resistance Using Reporter Expression

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the system for detection of microorganisms and antimicrobial resistance using reporter expression into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the system for detection of microorganisms and antimicrobial resistance using reporter expression's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective February 4, 2022. The classification was applicable on December 5, 2019.

FOR FURTHER INFORMATION CONTACT: Tobin Hellyer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3272, Silver Spring, MD 20993–0002, 301–796–6154, *Tobin.Hellyer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the system for detection of microorganisms and antimicrobial resistance using reporter expression as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a

common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 19, 2019, FDA received Roche Molecular Systems, Inc.'s request for De Novo classification of the cobas vivoDx MRSA. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 5, 2019, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 866.1655.[1] We have named the generic type of device system for detection of microorganisms and antimicrobial resistance using reporter expression, and it is identified as an in vitro diagnostic device intended for the detection and identification of live microorganisms and the detection of associated antimicrobial drug susceptibility or resistance in specimens from patients at risk of colonization or suspected of infection.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—SYSTEM FOR DETECTION OF MICROORGANISMS AND ANTIMICROBIAL RESISTANCE USING REPORTER EXPRESSION RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Failure to use the device correctly	Certain labeling information identified in special controls (b)(1) and (3), and Certain design verification and validation identified in special control (b)(4)(vii).
False positive or negative results	Certain labeling information identified in special controls (b)(1) and (3), Use of certain specimen collection and transport devices identified in special control (b)(2), and Certain design verification and validation identified in special control (b)(4).
Failure to interpret results correctly	Certain labeling information identified in special controls (b)(1) and (3), and Certain design verification and validation identified in special control (b)(4)(vii).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget

[1] FDA notes that the **ACTION** caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

(OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 866.1655 to subpart B to read as follows:

§ 866.1655 System for detection of microorganisms and antimicrobial resistance using reporter expression.

(a) *Identification.* A system for detection of microorganisms and antimicrobial resistance using reporter expression is an in vitro diagnostic device intended for the detection and identification of live microorganisms and the detection of associated antimicrobial drug susceptibility or resistance in specimens from patients at risk of colonization or suspected of infection.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The intended use for the device in the labeling required under § 809.10 of this chapter must include a detailed description of the targets the device detects, the type of results provided to the user, the clinical indications appropriate for test use, and the specific population(s) for which the device is intended.

(2) Any device used for specimen collection and transport must be FDA-cleared, approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of the specimen types claimed by this device and for the maintenance of viability of the targeted microorganisms; alternatively, the specimen collection device must be cleared in a premarket submission as a part of this device.

(3) The labeling required under § 809.10(b) of this chapter must include:

(i) A detailed description of the device, including reagents, instruments, ancillary materials, applicable specimen collection and transport device(s) and control elements, and a detailed explanation of the methodology, including all pre-analytical methods for handling and processing of specimens and controls to maintain organism viability;

(ii) Detailed descriptions of the test procedure, including the preparation and maintenance of quality controls and the interpretation of test results;

(iii) Detailed discussion of the performance characteristics of the device for all claimed organisms and specimen types based on analytical studies, including evaluation of analytical sensitivity, inclusivity, cross-reactivity, potentially interfering substances and microorganisms, contamination, specimen stability, precision, and reproducibility;

(iv) Detailed discussion of the performance characteristics of the device observed in a clinical study performed on a population that is consistent with the intended use population in comparison to the results obtained by a reference or comparator method determined to be acceptable by FDA, for microbial detection, identification, and antimicrobial susceptibility testing; and

(v) A limiting statement indicating that a negative test result does not preclude colonization or infection with organisms that do not express detectable levels of the reporter that is identified by the device.

(4) Design verification and validation must include:

(i) A detailed description of the device, including an explanation of the technology, hardware, software, and consumables, as well as an explanation of the result algorithms and method(s) of data processing from signal acquisition to result assignment;

(ii) A detailed description of the impact of any software, including software applications and hardware-based devices that incorporate software, on the device's functions;

(iii) Detailed documentation of the analytical and clinical studies required in paragraphs (b)(3)(iii) and (iv) of this section, including the study protocols containing descriptions of the test methods, prescribed methods of data analysis and acceptance criteria, final study reports, and data line listings;

(iv) Detailed documentation of quality control procedures, including an explanation of how quality control materials were selected, the recommended frequency of testing, methods of control preparation, acceptance criteria for performance and the results from quality control testing performed during the analytical and clinical studies required under paragraphs (b)(3)(iii) and (iv) of this section;

(v) Detailed documentation of studies performed to establish onboard and in-use reagent stability, including the test method(s), data analysis plans, acceptance criteria, final study reports, and data line listings;

(vi) Detailed documentation of studies to establish reagent shelf-life for the assay kit and each applicable specimen collection and transport device, including study protocols containing descriptions of the test method(s), data analysis plans, and acceptance criteria; and

(vii) Documentation of an appropriate end user device training program that will be offered as part of efforts to assure appropriate conduct of the assay and to mitigate the risk associated with false results, including failure to use the device correctly or correctly interpret results.

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02368 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2021–N–0913]

Medical Devices; Cardiovascular Devices; Classification of the Photoplethysmograph Analysis Software for Over-the-Counter Use

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the photoplethysmograph analysis software for over-the-counter use into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the photoplethysmograph analysis software for over-the-counter use's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective February 4, 2022. The classification was applicable on September 11, 2018.

FOR FURTHER INFORMATION CONTACT: Jennifer Kozen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2272, Silver Spring, MD 20993–0002, 301–796–5813, *Jennifer.Shih@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the photoplethysmograph analysis software for over-the-counter use as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On August 9, 2018, FDA received Apple Inc.'s request for De Novo classification of the Irregular Rhythm Notification Feature. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on September 11, 2018, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 870.2790.[1] We have named the generic type of device photoplethysmograph analysis software for over-the-counter use, and it is identified as a device that analyzes photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a diagnosis.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the **ACTION** caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—PHOTOPLETHYSMOGRAPH ANALYSIS SOFTWARE FOR OVER-THE-COUNTER USE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Poor quality incoming photoplethysmograph (PPG) signal resulting in failure to detect irregular heart rhythms.	Clinical performance testing, Human factors testing, and Labeling.
Misinterpretation and/or over-reliance on device output, leading to: • Failure to seek treatment despite acute symptoms (*e.g.,* fluttering sensation in the chest, lightheadedness, and irregular pulse). • Discontinuing or modifying treatment for chronic heart condition.	Human factors testing, and Labeling.
False negative resulting in failure to detect irregular heart rhythms and delay of further evaluation or treatment.	Clinical performance testing; Software verification, validation, and hazard analysis; Non-clinical performance testing; and Labeling.
False positive resulting in additional unnecessary medical procedures ..	Clinical performance testing; Software verification, validation, and hazard analysis; Non-clinical performance testing; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 870.2790 to subpart C to read as follows:

§ 870.2790 Photoplethysmograph analysis software for over-the-counter use.

(a) *Identification.* A photoplethysmograph analysis software device for over-the-counter use analyzes photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a diagnosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate the performance characteristics of the detection algorithm under anticipated conditions of use.

(2) Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

(3) Non-clinical performance testing must demonstrate the ability of the device to detect adequate photoplethysmograph signal quality.

(4) Human factors and usability testing must demonstrate the following:

(i) The user can correctly use the device based solely on reading the device labeling; and

(ii) The user can correctly interpret the device output and understand when to seek medical care.

(5) Labeling must include:

(i) Hardware platform and operating system requirements;

(ii) Situations in which the device may not operate at an expected performance level;

(iii) A summary of the clinical performance testing conducted with the device;

(iv) A description of what the device measures and outputs to the user; and

(v) Guidance on interpretation of any results.

Dated: January 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02358 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2021–N–0948]

Medical Devices; General and Plastic Surgery Devices; Classification of the Carbon Dioxide Gas Controlled Tissue Expander

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the carbon dioxide gas

controlled tissue expander into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the carbon dioxide gas controlled tissue expander's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective February 4, 2022. The classification was applicable on December 21, 2016.

FOR FURTHER INFORMATION CONTACT: Tajanay Ki, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4553, Silver Spring, MD 20993–0002, 301–796–6441, *Tajanay.Ki@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the carbon dioxide gas controlled tissue expander as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513 c(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 8, 2015, FDA received AirXpanders' request for De Novo classification of the AeroForm® Tissue Expander System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 21, 2016, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 878.3510.[1] We have named the generic type of device carbon dioxide gas-controlled tissue expander, and it is identified as a prescription device intended for temporary subcutaneous or submuscular implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. The device is made of an inflatable elastomer shell and is filled with carbon dioxide gas. The device utilizes a remote controller to administer doses of carbon dioxide gas from an implanted canister inside the device.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the **ACTION** caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—CARBON DIOXIDE GAS CONTROLLED TISSUE EXPANDER RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Pain	Labeling; and
• From overexpansion with carbon dioxide	Software verification, validation and hazard analysis.
Tissue damage	In-vivo performance testing; Labeling; and
• From overexpansion with carbon dioxide	Software verification, validation and hazard analysis.
Prolonged treatment time	In-vivo performance testing;
• Due to under expansion because of carbon dioxide permeation	Non-clinical performance testing; Labeling; and
• Due to overexpansion with carbon dioxide	Software verification, validation and hazard analysis.
Re-operation	In-vivo performance testing and Non-clinical performance testing.
• Due to no expansion because of device failure	
• Due to overexpansion with carbon dioxide	
Under expansion, overexpansion, or no expansion	Electromagnetic compatibility, electrical safety, and wireless compatibility testing; Labeling;
• Due to interference with other devices	Software verification, validation and hazard analysis;
• Due to user error	Human factors testing; and Patient training.
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Sterilization validation and Shelf life testing.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, carbon dioxide gas controlled tissue expanders are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 878.3510 to subpart D to read as follows:

§ 878.3510 Carbon dioxide gas controlled tissue expander.

(a) *Identification.* A carbon dioxide gas controlled tissue expander is a prescription device intended for temporary subcutaneous or submuscular implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. The device is made of an inflatable elastomer shell and is filled with carbon dioxide gas. The device utilizes a remote controller to administer doses of carbon dioxide gas from an implanted canister inside the device.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) In-vivo performance testing must be conducted to obtain the adverse event profile associated with use, and demonstrate that the device performs as intended under anticipated conditions of use.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate the sterility of patient-contacting components of the device.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Cycle testing of expander showing that there are no leaks or tears after repeated cycling;

(ii) Mechanical assessment of implanted carbon dioxide (CO_2) canister including high impact testing;

(iii) Leak testing of expander showing that device does not leak CO_2;

(iv) Assessment of gas permeability during expansion and after full expansion; and

(v) Mechanical assessment of expander (tensile set, breaking force, shell joint test, and fused or adhered joint testing).

(5) Performance data must be provided to demonstrate the electromagnetic compatibility, electrical safety, and wireless compatibility of the device.

(6) Software verification, validation, and hazard analysis must be performed.

(7) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components, package integrity, and device functionality over the identified shelf life.

(8) Human factors testing and analysis must validate that the device design and labeling are sufficient for the end user.

(9) Physician labeling must include:

(i) The operating parameters, name, and model number of the indicated external dosage controller;

(ii) Information on how the device operates and the typical course of treatment;

(iii) Information on the population for which the device has been demonstrated to be effective;

(iv) A detailed summary of the device technical parameters; and

(v) Provisions for choosing an appropriate size implant that would be exchanged for the tissue expander.

(10) Patient labeling must include:

(i) Warnings, precautions, and contraindications, and adverse events/complications;

(ii) Information on how the device operates and the typical course of treatment;

(iii) The probable risks and benefits associated with the use of the device;

(iv) Post-operative care instructions; and

(v) Alternative treatments.

(11) Patient training must include instructions for device use, when it may be necessary to contact a physician, and cautionary measures to take when the device is implanted.

Dated: January 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02357 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2021–N–0998]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Alternate Controller Enabled Infusion Pump

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the alternate controller enabled infusion pump into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the alternate controller enabled infusion pump's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES:

Effective date: This order is effective February 4, 2022.

Applicability date: The classification was applicable on February 14, 2019.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 240–402–6357, *Ryan.Lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the alternate controller enabled infusion pump as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 29, 2018, FDA received Tandem Diabetes Care, Inc.'s request for De Novo classification of the t:slim X2

insulin pump with interoperable technology. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the generals controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 14, 2019, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 880.5730.[1] We have named the generic type of device ''alternate controller enabled infusion pump,'' and it is identified as an alternate controller enabled infusion pump (ACE pump). The ACE pump is a device intended for the infusion of drugs into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. ACE pumps are designed to reliably and securely communicate with external devices, such as automated drug dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE pumps are intended to be used both alone and in conjunction with digitally connected devices for the purpose of drug delivery.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ALTERNATE CONTROLLER ENABLED INFUSION PUMP RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Patient harm due to inadequate drug delivery accuracy that leads to over infusion or under infusion of drug.	Basal and bolus drug delivery accuracy validation testing, Device use life reliability testing, Design mitigations to prevent cross-channeling. Validated and traceable risk control measures for identified hazards.
Patient harm due to undetected pump occlusions that pose risk of under infusion of drug.	Hazard detection (*e.g.,* drug occlusion) validation testing.
Patient harm due to incompatibility between the drug and the pump that may lead to over infusion or under infusion of drug, or exposure to harmful substances leached from pump materials into the infused drug solution.	Drug compatibility testing.
Inability to provide appropriate treatment due to loss of communication with digitally connected alternate pump controller devices.	Validated communication specifications, processes, and procedures with digitally connected devices.
Commands from the digitally connected alternate pump controller devices that conflict with existing pump commands may lead to unintended over or under infusion of drug.	Validated communication specifications, processes, and procedures with digitally connected devices, Validated failsafe design features.
Conflicting interfaces resulting in over or under delivery	Validated communication specifications, processes, and procedures with digitally connected devices, Validated failsafe design features.
Patient harm due to insecure transmission of data	Validated communication specifications, processes, and procedures with digitally connected devices.
Patient harm due to inability to determine source of dosing error when used in an integrated system.	Validated data logging capability.
Patient harm due to exposure to hazardous and non-biocompatible materials or pathogens.	Biocompatibility testing, Validation of reprocessing procedures.
Patient harm due to data transmission interference/electromagnetic disturbance.	Electrical safety, electromagnetic compatibility, and radio frequency wireless safety testing.
Patient harm due to incorrect use of pump, operational, and/or use-related errors.	Human Factors testing, Transparent pump performance descriptions in labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of

[1] FDA notes that the **ACTION** caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding the quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 880.5730 to subpart F to read as follows:

§ 880.5730 Alternate controller enabled infusion pump.

(a) *Identification.* An alternate controller enabled infusion pump (ACE pump) is a device intended for the infusion of drugs into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. ACE pumps are designed to reliably and securely communicate with external devices, such as automated drug dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE pumps are intended to be used both alone and in conjunction with digitally connected medical devices for the purpose of drug delivery.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include the following:

(i) Evidence demonstrating that device infusion delivery accuracy conforms to defined user needs and intended uses and is validated to support safe use under actual use conditions.

(A) Design input requirements must include delivery accuracy specifications under reasonably foreseeable use conditions, including ambient temperature changes, pressure changes (*e.g.,* head-height, backpressure, atmospheric), and, as appropriate, different drug fluidic properties.

(B) Test results must demonstrate that the device meets the design input requirements for delivery accuracy under use conditions for the programmable range of delivery rates and volumes. Testing shall be conducted with a statistically valid number of devices to account for variation between devices.

(ii) Validation testing results demonstrating the ability of the pump to detect relevant hazards associated with drug delivery and the route of administration (*e.g.,* occlusions, air in line, etc.) within a clinically relevant timeframe across the range of programmable drug delivery rates and volumes. Hazard detection must be appropriate for the intended use of the device and testing must validate appropriate performance under the conditions of use for the device.

(iii) Validation testing results demonstrating compatibility with drugs that may be used with the pump based on its labeling. Testing must include assessment of drug stability under reasonably foreseeable use conditions that may affect drug stability (*e.g.,* temperature, light exposure, or other factors as needed).

(iv) The device parts that directly or indirectly contact the patient must be demonstrated to be biocompatible. This shall include chemical and particulate characterization on the final, finished, fluid contacting device components demonstrating that risk of harm from device-related residues is reasonably low.

(v) Evidence verifying and validating that the device is reliable over the ACE pump use life, as specified in the design file, in terms of all device functions and in terms of pump performance.

(vi) The device must be designed and tested for electrical safety, electromagnetic compatibility, and radio frequency wireless safety and availability consistent with patient safety requirements in the intended use environment.

(vii) For any device that is capable of delivering more than one drug, the risk of cross-channeling drugs must be adequately mitigated.

(viii) For any devices intended for multiple patient use, testing must demonstrate validation of reprocessing procedures and include verification that the device meets all functional and performance requirements after reprocessing.

(2) Design verification and validation activities must include appropriate design inputs and design outputs that are essential for the proper functioning of the device that have been documented and include the following:

(i) Risk control measures shall be implemented to address device system hazards and the design decisions related to how the risk control measures impact essential performance shall be documented.

(ii) A traceability analysis demonstrating that all hazards are adequately controlled and that all controls have been validated in the final device design.

(3) The device shall include validated interface specifications for digitally connected devices. These interface specifications shall, at a minimum, provide for the following:

(i) Secure authentication (pairing) to external devices.

(ii) Secure, accurate, and reliable means of data transmission between the pump and connected devices.

(iii) Sharing of necessary state information between the pump and any digitally connected alternate controllers (*e.g.,* battery level, reservoir level, pump status, error conditions).

(iv) Ensuring that the pump continues to operate safely when data is received in a manner outside the bounds of the parameters specified.

(v) A detailed process and procedure for sharing the pump interface specification with digitally connected devices and for validating the correct implementation of that protocol.

(4) The device must include appropriate measures to ensure that safe therapy is maintained when communications with digitally connected alternate controller devices is interrupted, lost, or re-established after an interruption (*e.g.,* reverting to a pre-programmed, safe drug delivery rate). Validation testing results must demonstrate that critical events that occur during a loss of communications (*e.g.,* commands, device malfunctions, occlusions, etc.) are handled appropriately during and after the interruption.

(5) The device design must ensure that a record of critical events is stored and accessible for an adequate period to allow for auditing of communications between digitally connected devices and to facilitate the sharing of pertinent information with the responsible parties for those connected devices. Critical events to be stored by the system must, at a minimum, include:

(i) A record of all drug delivery

(ii) Commands issued to the pump and pump confirmations

(iii) Device malfunctions

(iv) Alarms and alerts and associated acknowledgements

(v) Connectivity events (*e.g.,* establishment or loss of communications)

(6) Design verification and validation must include results obtained through a

human factors study that demonstrates that an intended user can safely use the device for its intended use.

(7) Device labeling must include the following:

(i) A prominent statement identifying the drugs that are compatible with the device, including the identity and concentration of those drugs as appropriate.

(ii) A description of the minimum and maximum basal rates, minimum and maximum bolus volumes, and the increment size for basal and bolus delivery, or other similarly applicable information about drug delivery parameters.

(iii) A description of the pump accuracy at minimum, intermediate, and maximum bolus delivery volumes and the method(s) used to establish bolus delivery accuracy. For each bolus volume, pump accuracy shall be described in terms of the number of bolus doses measured to be within a given range as compared to the commanded volume. An acceptable accuracy description (depending on the drug delivered and bolus volume) may be provided as follows for each bolus volume tested, as applicable: Number of bolus doses with volume that is <25 percent, 25 percent to <75 percent, 75 percent to <95 percent, 95 percent to <105 percent, 105 percent to <125 percent, 125 percent to <175 percent, 175 to 250 percent, and >250 percent of the commanded amount.

(iv) A description of the pump accuracy at minimum, intermediate, and maximum basal delivery rates and the method(s) used to establish basal delivery accuracy. For each basal rate, pump accuracy shall be described in terms of the amount of drug delivered after the basal delivery was first commanded, without a warmup period, up to various time points. The information provided must include typical pump performance, as well as worst-case pump performance observed during testing in terms of both over-delivery and under-delivery. An acceptable accuracy description (depending on the drug delivered) may be provided as follows, as applicable: The total volume delivered 1 hour, 6 hours, and 12 hours after starting delivery for a typical pump tested, as well as for the pump that delivered the least and the pump that delivered the most at each time point.

(v) A description of delivery hazard alarm performance, as applicable. For occlusion alarms, performance shall be reported at minimum, intermediate, and maximum delivery rates and volumes. This description must include the specification for the longest time period that may elapse before an occlusion alarm is triggered under each delivery condition, as well as the typical results observed during performance testing of the pumps.

(vi) For wireless connection enabled devices, a description of the wireless quality of service required for proper use of the device.

(vii) For any infusion pumps intended for multiple patient reuse, instructions for safely reprocessing the device between uses.

Dated: January 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02369 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ97

Informed Consent and Advance Directives

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) published an interim final rule amending its regulation regarding informed consent and advance directives. In that rulemaking, we amended the regulation by reorganizing it and amending language where necessary to enhance clarity. We also made changes to facilitate the informed consent process, the ability to communicate with patients or surrogates through available modalities of communication, and the execution and witness requirements for a VA Advance Directive. Before adopting that interim final rule as final, VA revises the provision related to which personnel may be delegated the responsibility for providing a patient with information needed for the patient to make a fully informed consent decision. Upon further review, VA has determined that this provision requires a further change to better clarify roles in the team-based delivery of care model. We are providing the public an opportunity to submit comments solely on this amendment.

DATES:

Effective date: This interim final rule is effective February 4, 2022.

Comments due date: Comments must be received on or before April 5, 2022.

ADDRESSES: Comments may be submitted through *www.Regulations.gov.* Comments received will be available at *regulations.gov* for public viewing, inspection, or copies.

FOR FURTHER INFORMATION CONTACT: Lucinda Potter, LSW, Acting Director of Ethics Policy, National Center for Ethics in Health Care (10ETH), Veterans Health Administration, 810 Vermont Ave. NW, Washington, DC 20420; 484–678–5150. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: In an interim final rule published May 27, 2020 (85 FR 31690), we amended 38 CFR 17.32, our regulation addressing informed consent for treatments and procedures, by reorganizing it and amending language where necessary to enhance clarity. We also made changes to facilitate the informed consent process, the ability to communicate with patients or surrogates through available modalities of communication, and the execution and witnessing for a VA Advance Directive. We amended the definition of ''practitioner'' to include other health care professionals whose scope of practice agreement or other formal delineation of job responsibility specifically permits them to obtain informed consent, and who are appropriately trained and authorized to perform the procedure or to provide the treatment for which consent is being obtained.

Under the previous informed consent rule, the practitioner, who had primary responsibility for the patient or who would perform the particular procedure or provide the treatment, was responsible for explaining in language understandable to the patient or surrogate the nature of a proposed procedure or treatment; the expected benefits; reasonably foreseeable associated risks, complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done. There was no provision in the rule addressing the question of whether, consistent with a team-based delivery of care model, appropriately trained health care team members had a role in the informed consent process. In the May 2020 interim final rule, we dealt with that issue in paragraph (c)(6), stating that the practitioner may delegate to other trained personnel responsibility for providing the patient with clinical information needed for the patient to make a fully informed consent decision but must personally verify with the patient that the patient has been appropriately informed and voluntarily consents to the treatment or procedure.

VA intended that paragraph (c)(6) give the practitioner discretion to more fully utilize the training and expertise of non-practitioners within the bounds of the

team-based care model. Upon further review, VA has determined that this paragraph should be amended to more clearly reflect VA's intent to utilize a team-based approach for other elements of informed consent discussions in addition to provision of information to the patient. Consistent with longstanding VA policy and practice, we amend paragraph (c)(6) to more broadly state that trained personnel may conduct elements of the informed consent process when delegated by the practitioner.

We are also removing the term ''clinical information'' in this paragraph. We believe the term ''clinical information'' in the current paragraph (c)(6) could be problematic. It is not defined in VA regulations and is used only in VA policy documents either generically (to describe any health information reflected in medical records) or to describe specific types of stored information such as medical-related data, images, sound, and video related to certain types of medical examinations. ''Clinical information'' could also be narrowly used to describe only technical information related to a treatment or procedure. A narrow construction and application of that term is counter to the team model which is intended to benefit the patient by allowing members of the health care team to provide necessary information through different perspectives. This model also provides the patient an opportunity to freely communicate with not only the practitioner but also with other team members regarding the proposed treatment or procedure.

Based on that rationale, we amend paragraph (c)(6) to clarify that the practitioner may delegate to trained personnel the responsibility of conducting elements of the informed consent process beyond simply providing information. To ensure that clinical oversight is retained, the practitioner remains responsible for the informed consent process and must personally verify with the patient that the patient has been fully informed and voluntarily consents to the treatment or procedure. Elements of the informed consent process that may be delegated to trained personnel include providing patient education regarding the proposed treatment or procedure, identifying the authorized surrogate for patients who lack decision-making capacity, and assisting with obtaining the patient's (or surrogate's) signature for treatments and procedures that require signature informed consent.

VA believes that this will ensure that elements of informed consent discussions that may be appropriately delegated by providers are not unduly limited by regulation, while still making clear that the practitioner remains responsible for the informed consent process and for personally verifying with the patient that the patient has been fully informed and voluntarily consents to the treatment or procedure.

We are providing a 60-day period for submission of comments from the public on this amendment of § 17.32(c)(6). We are not accepting any public comment on any other content in § 17.32. Following the 60-day public comment period, we will review and consider comments received and then publish a final rulemaking capturing not only this interim final rule but also the May 2020 interim final rule.

Administrative Procedure Act

The Secretary of Veterans Affairs finds that there is good cause under the provisions of 5 U.S.C. 553(b)(B), to publish this amendment as an interim final rule without prior notice and the opportunity for public comment, and under 5 U.S.C. 553(d)(3), to dispense with the delayed effective date ordinarily prescribed by the Administrative Procedure Act (APA).

Pursuant to section 553(b)(B) of the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an ''agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' The Secretary finds that it is impractical to delay issuance of this rule for the purpose of soliciting prior public comment because there is an immediate and pressing need for VA to respond to the current public health crisis and national emergency by ensuring effective use of health care resources as part of the announced VA contingent/crisis standards of care, in addition to regular standards of care provided to eligible beneficiaries. VA believes members of a VA health care team should be utilized to the fullest extent practicable in providing veterans information on risks and benefits of proposed treatments or procedures. Thus, delaying the implementation of this clarifying amendment would be contrary to the public interest.

For these reasons, the Secretary has concluded that ordinary notice and comment procedures would be both impracticable and contrary to the public interest. Accordingly, VA issues this amendment as a separate interim final rule. The Secretary will consider and address comments that are received within 60 days after the date that this interim final rule is published in the **Federal Register** and address them in a subsequent **Federal Register** document announcing a final rule incorporating any changes made in response to the public comments on this interim final rule and the May 2020 interim final rule.

The APA also requires a 30-day delayed effective date, except for ''(1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule.'' 5 U.S.C. 553(d). For the reasons stated above, the Secretary finds that there is also good cause for this interim rule to be effective immediately upon publication. It is in the public interest for VA to immediately adopt the process changes noted above to provide for effective utilization of VA practitioners as it relates to the informed consent process during this period of increased demand for health care, to provide flexibility to utilize alternative modalities of communications during the COVID–19 National Emergency, and to facilitate veterans documenting treatment preferences in an advance directive. By immediately making necessary process changes, the Secretary finds good cause to exempt this amendment from the APA's delayed effective date requirement.

Paperwork Reduction Act

Although this action contains provisions constituting collections of information, at 38 CFR 17.32, under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), no new or proposed revised collections of information are associated with this interim final rule. The information collection requirements for § 17.32 are currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 2900–0556.

Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612, because it affects only the informed consent process and use of advance directives within the VA health care system.

Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. The amendment issued here as an interim final rule will not result in the expenditure of $100 million or more by State, local, and tribal governments, in the aggregate, or by the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Assistance Listing

The Assistance Listing program numbers and titles for the programs affected by this document are 64.008—Veterans Domiciliary Care; 64.011—Veterans Dental Care; 64.012—Veterans Prescription Service; 64.013—Veterans Prosthetic Appliances; 64.014—Veterans State Domiciliary Care; 64.015—Veterans State Nursing Home Care; 64.024—VA Homeless Providers Grant and Per Diem Program; 64.026—Veterans State Adult Day Health Care; 64.029—Purchase Care Program; 64.039—CHAMPVA; 64.040—VHA Inpatient Medicine; 64.041—VHA Outpatient Specialty Care; 64.042—VHA Inpatient Surgery; 64.043—VHA Mental Health Residential; 64.044—VHA Home Care; 64.045—VHA Outpatient Ancillary Services; 64.046—VHA Inpatient Psychiatry; 64.047—VHA Primary Care; 64.048—VHA Mental Health clinics; 64.049—VHA Community Living Center; 64.050—VHA Diagnostic Care; 64.054—Research and Development.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on January 31, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

■ 2. Amend § 17.32 by revising paragraph (c)(6) to read as follows:

§ 17.32 Informed consent and advance directives.

* * * * *

(c) * * *

(6) Trained personnel may conduct elements of the informed consent process when delegated by the practitioner. However, the practitioner remains responsible for the informed consent process and must personally verify with the patient that the patient has been fully informed and voluntarily consents to the treatment or procedure.

* * * * *

[FR Doc. 2022–02316 Filed 2–3–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

Clarification Concerning Tuition and Fees Payment Plans for Standard Terms and 85/15 Calculations

AGENCY: Department of Veterans Affairs.

ACTION: Policy interpretation.

SUMMARY: The Department of Veterans Affairs (VA) provides notice of a policy advisory issued on August 31, 2021, by VA's Education Service. The policy advisory clarifies and amends VA's previous regulatory interpretation of tuition and fees (T&F) payment plans to differentiate between types of payment plans. Some payment plans should no longer be categorized as institutional support to a student when calculating the ratio of ''supported'' to ''non-supported'' students in a program pursuant to the 85/15 Rule. While VA is retaining the general rule that a student who has a payment plan with an Educational Training Institute (ETI) should be considered supported, a student participating in a payment plan that meets the criteria set forth in this notice should *not* be considered supported and, instead, should be counted on the non-supported side of the 85/15 ratio.

DATES: This policy interpretation is applicable from February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Cheryl Amitay, Chief of Policy and Regulations Team, Education Service (225), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, Telephone: 202–461–9800 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The 85/15 rule (38 U.S.C. 3680A(d); 38 CFR 21.4201(a)) prohibits VA from paying educational assistance benefits to any new students once ''more than 85 percent of the students enrolled in the [program of education] are having all or part of their tuition, fees or other charges paid to or for them by the educational institution or by the Department of Veterans Affairs'' (38 U.S.C. 3680A(d)(1)). VA refers to students who receive such institutional or VA aid as ''supported'' students. Conversely, no less than 15 percent of the students enrolled in the program must be attending without having any of their tuition, fees or other charges paid to or for them by the educational institution or VA (referred to as non-supported students).

Currently, in accordance with 38 CFR 21.4201, educational institutions are

required to track the percentage of supported and non-supported students enrolled in each of their approved programs and to confirm their compliance with the required 85/15 percent ratio (38 CFR 21.4201(e)–(f)). During the time the ratio of supported students to non-supported students exceeds 85 percent, no new students can be certified to receive VA education benefits for that program (38 CFR 21.4201(g)(2)). For the 85/15 calculations, new students include students returning after a break in enrollment unless the break is wholly due to circumstances beyond the student's control (38 CFR 21.4201(g)(6)). The 85/15 rule allows VA to continue to pay benefits for students already enrolled in the program and receiving benefits prior to the ratio of supported students exceeding 85 percent of the total population enrolled in the program (38 CFR 21.4201(g)(2)).

A program suspended for violating the 85/15 rule still may retain all of its current students. VA beneficiaries already enrolled in the program will be allowed to receive benefits for the program as long as they remain continuously enrolled, even if the ratio of supported students rises above 85 percent. Also, a beneficiary enrolled at an educational institution organized on a term, semester or quarter basis need not attend summer sessions to maintain continuous enrollment. Further, as provided in 38 U.S.C. 3680A(d) and 38 CFR 21.4201, any school is permitted to request a waiver from 85/15 reporting. Finally, there are exceptions to compliance with the 85/15 rule, such as the following:

- VA beneficiaries receiving Veteran Readiness and Employment (Chapter 31), or Survivors' and Dependents' Educational Assistance (Chapter 35) benefits.
- Certain types of education and training institutions such as high schools, aero clubs, and farm cooperative courses.
- Sites approved for on-the-job or apprenticeship training.

In 2020, the VA Education Service informed schools that a student who has a payment plan with an ETI also should be considered supported for calculating the 85/15 ratio. After consulting with various partners as well as striving to interpret T&F payment plans in a manner which balances the best interests of students with the statutory mandate of the 85/15 rule, VA amended its guidance regarding payment plans at ETIs in a policy advisory issued on August 31, 2021: Clarification Concerning Tuition and Fees Payment Plans for Standard Terms and 85/15 Calculations. The policy set forth in the aforementioned advisory is as follows:

For classifying a student as supported or non-supported on VA form 22–10215, Statement of Assurance of Compliance with 85/15 Enrollment Ratios, a student enrolled in an ETI will be considered to be supported by the ETI unless *all* of the following apply (*i.e.,* if *all* of the following apply the student will be considered non-supported):

1. The availability and requirements of the payment plan are available for review and/or inspection by students, the State approving agency and VA (a) on the school's website and (b) in a dated hard copy on file at every campus of the ETI.

2. The ETI T&F payment plan includes the following provisions:

a. The payment plan is available to any enrolled student who is interested in participating.

b. The payment plan explicitly requires the student to pay the outstanding balance by the end of the 85/15 reporting period (academic term or calendar quarter) (*i.e.,* the ETI requires the payment plan to be paid off in full no later than the end of the term).

c. The payment plan must be paid in full before students can begin training for the next term.

To reiterate, unless *all* of the aforementioned conditions are met by the ETI and its T&F payment plan, the school's payment plan will still be considered a source of institutional support and should still be reported on the supported student count side of the 85/15 supported to non-supported ratio (*i.e.,* the side that cannot exceed 85%). Conversely, if all of the aforementioned apply, the T&F payment plan should not be construed as providing institutional support so a student participating in one is *not* to be considered supported and should be reported on the non-supported side of the 85/15 ratio (*i.e.,* the side that must be at least 15%).

The 85/15 rule ensures a minimum number of students who are not receiving VA funds are willing to pay for the full cost of the program to ensure the price of the program responds to the general demands of the open market and a minimum number of non-VA beneficiaries find the program worthwhile and valuable. VA cannot ensure compliance with the 85/15 rule nor ensure GI Bill beneficiaries are not being overcharged if there is an unpaid balance at the end of the reporting period that could subsequently be waived or otherwise written off.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on January 28, 2022 and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2022–02305 Filed 2–3–22; 8:45 am]

BILLING CODE 8320–01–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3040

[Docket No. RM2020–8]

Update to Competitive Product List

AGENCY: Postal Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The Commission is announcing an update to the competitive product list. This action reflects a publication policy adopted by Commission rules. The referenced policy assumes periodic updates. The updates are identified in the body of this document. The competitive product list, which is re-published in its entirety, includes these updates.

DATES: This rule is effective March 21, 2022, without further action, unless adverse comment is received by March 7, 2022. If adverse comment is received, the Commission will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: For additional information, this document can be accessed electronically through the Commission's website at *https://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6800.

SUPPLEMENTARY INFORMATION:

I. Introduction
II. Commission Process
III. Authorization
IV. Modifications
V. Ordering Paragraphs

I. Introduction

Pursuant to 39 U.S.C. 3642(d)(2) and 39 CFR 3040.103, the Commission provides an Update to Competitive Product List by listing all necessary modifications to the competitive product list between October 1, 2021 and December 31, 2021.

II. Commission Process

Pursuant to 39 CFR part 3040, the Commission maintains a Mail

Classification Schedule (MCS) that includes rates, fees, and product descriptions for each market dominant and competitive product, as well as product lists that categorize Postal Service products as either market dominant or competitive. *See generally* 39 CFR part 3040. The product lists are published in the Code of Federal Regulations as 39 CFR Appendix A to Subpart A of Part 3040—Market Dominant Product List and Appendix B to Subpart A of Part 3040—Competitive Product List pursuant to 39 U.S.C. 3642(d)(2). *See* 39 U.S.C. 3642(d)(2). Both the MCS and its product lists are updated by the Commission on its website on a quarterly basis.[1] In addition, these quarterly updates to the product lists are also published in the **Federal Register** pursuant to 39 CFR 3040.103. *See* 39 CFR 3040.103.

III. Authorization

Pursuant to 39 CFR 3040.103(d)(1), this Update to Product Lists identifies any modifications made to the market dominant or competitive product list, including product additions, removals, and transfers.[2] Pursuant to 39 CFR 3040.103(d)(2), the modifications identified in this document result from the Commission's most recent MCS update posted on the Commission's website on January 9, 2022, and supersede all previous product lists.[3]

IV. Modifications

The following list of products is being added to 39 CFR Appendix B to Subpart A of Part 3040—Competitive Product List:

1. First-Class Package Service Contract 118
2. Parcel Select Contract 48
3. Parcel Select & Parcel Return Service Contract 14
4. Priority Mail Contract 721
5. Priority Mail Contract 722
6. Priority Mail Contract 723
7. Priority Mail Contract 724
8. Priority Mail Contract 725
9. Priority Mail Contract 726
10. Priority Mail Contract 727
11. Priority Mail Contract 728
12. Priority Mail Contract 729
13. Priority Mail Contract 730
14. Priority Mail Contract 731
15. Priority Mail Contract 732
16. Priority Mail Contract 733
17. Priority Mail Contract 734
18. Priority Mail & First-Class Package Service Contract 202
19. Priority Mail & First-Class Package Service Contract 203
20. Priority Mail & First-Class Package Service Contract 204
21. Priority Mail & First-Class Package Service Contract 205
22. Priority Mail & First-Class Package Service Contract 206
23. Priority Mail & First-Class Package Service Contract 207
24. Priority Mail & First-Class Package Service Contract 208
25. Priority Mail & First-Class Package Service Contract 209
26. Priority Mail & First-Class Package Service Contract 210
27. Priority Mail & First-Class Package Service Contract 211
28. Priority Mail & First-Class Package Service Contract 212
29. Priority Mail Express Contract 91
30. Priority Mail Express Contract 92
31. Priority Mail Express Contract 93
32. Priority Mail Express & Priority Mail Contract 126
33. Priority Mail Express & Priority Mail Contract 127
34. Priority Mail Express & Priority Mail Contract 128
35. Priority Mail Express, Priority Mail & First-Class Package Service Contract 77
36. Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 10
37. Priority Mail, First-Class Package Service & Parcel Select Contract 3

The following list of products is being removed from 39 CFR Appendix B to Subpart A of Part 3040—Competitive Product List:

1. First-Class Package Service Contract 94
2. Priority Mail Contract 438
3. Priority Mail Contract 469
4. Priority Mail Contract 474
5. Priority Mail Contract 478
6. Priority Mail Contract 486
7. Priority Mail Contract 487
8. Priority Mail Contract 488
9. Priority Mail Contract 490
10. Priority Mail Contract 495
11. Priority Mail Contract 497
12. Priority Mail Contract 499
13. Priority Mail Contract 503
14. Priority Mail Contract 553
15. Priority Mail Contract 635
16. Priority Mail Contract 675
17. Priority Mail Contract 683
18. Priority Mail & First-Class Package Service Contract 79
19. Priority Mail & First-Class Package Service Contract 83
20. Priority Mail & First-Class Package Service Contract 88
21. Priority Mail & First-Class Package Service Contract 98
22. Priority Mail & First-Class Package Service Contract 152
23. Priority Mail & First-Class Package Service Contract 156
24. Priority Mail & First-Class Package Service Contract 170
25. Priority Mail & First-Class Package Service Contract 179
26. Priority Mail & First-Class Package Service Contract 180
27. Priority Mail Express Contract 60
28. Priority Mail Express Contract 65
29. Priority Mail Express & Priority Mail Contract 72
30. Priority Mail Express & Priority Mail Contract 73
31. Priority Mail Express & Priority Mail Contract 101
32. Priority Mail Express & Priority Mail Contract 111
33. Priority Mail Express & Priority Mail Contract 119
34. Priority Mail Express & Priority Mail Contract 124
35. Priority Mail Express, Priority Mail & First-Class Package Service Contract 38
36. Priority Mail Express, Priority Mail & First-Class Package Service Contract 43
37. Priority Mail Express, Priority Mail & First-Class Package Service Contract 47
38. Priority Mail Express, Priority Mail & First-Class Package Service Contract 52

The above-referenced changes to the competitive product list are incorporated into 39 CFR Appendix B to Subpart A of Part 3040—Competitive Product List.

V. Ordering Paragraphs

It is ordered:

1. Part 3040 of title 39, Code of Federal Regulations, is amended as set forth below the signature of this rule, effective 45 days after the date of publication of the Notice in the **Federal Register** without further action, unless adverse comments are received.

2. The Secretary shall arrange for publication of this rule in the **Federal Register**.

3. Interested persons may submit adverse comments no later than 30 days from the date of the publication of this rule in the **Federal Register**.

4. If adverse comments are received, the Secretary will publish a timely withdrawal of the rule in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

List of Subjects in 39 CFR Part 3040

Administrative practice and procedure, Postal Service.

For the reasons discussed in the preamble, the Postal Regulatory Commission amends chapter III of title 39 of the Code of Federal Regulations as follows:

PART 3040—PRODUCT LISTS

■ 1. The authority citation for part 3040 continues to read as follows:

Authority: 39 U.S.C. 503; 3622; 3631; 3642; 3682.

[1] *See https://www.prc.gov/mail-classification-schedule* in the Current MCS section.

[2] 39 CFR 3040.103(d)(1). More detailed information (*e.g.,* Docket Nos., Order Nos., effective dates, and extensions) for each market dominant and competitive product can be found in the MCS, including the ''Revision History'' section. *See, e.g.,* file ''MCSRedline01092022.docx,'' available at *https://www.prc.gov/mail-classification-schedule.*

[3] Previous versions of the MCS and its product lists can be found on the Commission's website, available at *https://www.prc.gov/mail-classification-schedule* in the MCS Archives section.

■ 2. Revise Appendix A to Subpart A of Part 3040 to read as follows:

Appendix A to Subpart A of Part 3040—Market Dominant Product List

(An asterisk (*) indicates an organizational class or group, not a Postal Service product.)

FIRST–CLASS MAIL *

Single-Piece Letters/Postcards
Presorted Letters/Postcards
Flats
Outbound Single-Piece First-Class Mail International
Inbound Letter Post

USPS MARKETING MAIL (COMMERCIAL AND NONPROFIT) *

High Density and Saturation Letters
High Density and Saturation Flats/Parcels
Carrier Route
Letters
Flats
Parcels
Every Door Direct Mail—Retail

PERIODICALS *

In-County Periodicals
Outside County Periodicals

PACKAGE SERVICES *

Alaska Bypass Service
Bound Printed Matter Flats
Bound Printed Matter Parcels
Media Mail/Library Mail

SPECIAL SERVICES *

Ancillary Services
International Ancillary Services
Address Management Services
Caller Service
Credit Card Authentication
International Reply Coupon Service
International Business Reply Mail Service
Money Orders
Post Office Box Service
Stamp Fulfillment Services

NEGOTIATED SERVICE AGREEMENTS *

Domestic *
International *
Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators

NONPOSTAL SERVICES *

Alliances with the Private Sector to Defray Cost of Key Postal Functions
Philatelic Sales

MARKET TESTS *

Plus One
Commercial PO Box Redirect Service
Extended Mail Forwarding

■ 3. Revise Appendix B to Subpart A of Part 3040 to read as follows:

Appendix B to Subpart A of Part 3040—Competitive Product List

(An asterisk (*) indicates an organizational class or group, not a Postal Service product.)

DOMESTIC PRODUCTS *

Priority Mail Express
Priority Mail
Parcel Select
Parcel Return Service
First-Class Package Service
USPS Retail Ground

INTERNATIONAL PRODUCTS *

Outbound International Expedited Services
Inbound Parcel Post (at UPU rates)
Outbound Priority Mail International
International Priority Airmail (IPA)
International Surface Air Lift (ISAL)
International Direct Sacks–M-Bags
Outbound Single-Piece First-Class Package International Service
Inbound Letter Post Small Packets and Bulky Letters

NEGOTIATED SERVICE AGREEMENTS *

Domestic *
Priority Mail Express Contract 74
Priority Mail Express Contract 77
Priority Mail Express Contract 81
Priority Mail Express Contract 83
Priority Mail Express Contract 87
Priority Mail Express Contract 88
Priority Mail Express Contract 89
Priority Mail Express Contract 90
Priority Mail Express Contract 91
Priority Mail Express Contract 92
Priority Mail Express Contract 93
Parcel Return Service Contract 11
Parcel Return Service Contract 14
Parcel Return Service Contract 17
Parcel Return Service Contract 18
Priority Mail Contract 80
Priority Mail Contract 153
Priority Mail Contract 292
Priority Mail Contract 360
Priority Mail Contract 457
Priority Mail Contract 479
Priority Mail Contract 504
Priority Mail Contract 505
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Priority Mail Contract 731
Priority Mail Contract 732
Priority Mail Contract 733
Priority Mail Contract 734
Priority Mail Express & Priority Mail Contract 48

Priority Mail Express & Priority Mail Contract 84
Priority Mail Express & Priority Mail Contract 85
Priority Mail Express & Priority Mail Contract 88
Priority Mail Express & Priority Mail Contract 89
Priority Mail Express & Priority Mail Contract 90
Priority Mail Express & Priority Mail Contract 92
Priority Mail Express & Priority Mail Contract 95
Priority Mail Express & Priority Mail Contract 96
Priority Mail Express & Priority Mail Contract 99
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Advertising
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Mail Service Promotion
Officially Licensed Retail Products (OLRP)
Passport Photo Service
Photocopying Service
Rental, Leasing, Licensing or other Non-Sale Disposition of Tangible Property
Training Facilities and Related Services
USPS Electronic Postmark (EPM) Program

MARKET TESTS *

[FR Doc. 2022–02278 Filed 2–3–22; 8:45 am]

BILLING CODE 7710–FW–P

Proposed Rules

Federal Register
Vol. 87, No. 24
Friday, February 4, 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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[Docket No. PRM–50–119; NRC–2019–0083]

Access to the Decommissioning Trust Fund for the Disposal of Large Components

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking, dated February 22, 2019, submitted by Gerard P. Van Noordennen on behalf of EnergySolutions, LLC (the petitioner). The petition was docketed by the NRC on March 20, 2019, and was assigned Docket No. PRM–50–119. The petition requested that the NRC revise its regulations to allow access to the decommissioning trust fund for the removal of major radioactive components before the permanent cessation of operations and revise the definition of *Decommissioning.* The NRC is denying the petition because the petitioner does not raise a significant safety or security concern, and this subject area is adequately covered by existing regulations. The NRC's current regulations and oversight activities continue to provide for the reasonable assurance of adequate protection of public health and safety.

DATES: The docket for PRM–50–119 is closed on February 4, 2022.

ADDRESSES: Please refer to Docket ID NRC–2019–0083 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0083. Address questions about NRC Docket IDs to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** 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. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Solomon Sahle, telephone: 301–415–3781; email: *Solomon.Sahle@nrc.gov,* or Shawn Harwell, telephone: 301–415–1309; email: *Shawn.Harwell@nrc.gov.* Both are staff of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. The Petition

Section 2.802 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Petition for rulemaking—requirements for filing,'' provides an opportunity for any interested person to petition the NRC to issue, amend, or rescind any regulation. On February 22, 2019, the NRC received a petition for rulemaking (PRM) from Gerard P. Van Noordennen on behalf of EnergySolutions, LLC (ADAMS Accession No. ML19079A293). The petition requested the NRC revise the definition of *Decommissioning* in § 50.2, ''Definitions,'' and amend § 50.82, ''Termination of license,'' to allow access to the decommissioning trust fund to pay for the disposal of ''major radioactive components'' before the permanent cessation of operations at nuclear power plants. That term is currently defined in § 50.2: ''*Major radioactive components* means, for a nuclear power reactor facility, the reactor vessel and internals, steam generators, pressurizers, large bore reactor coolant system piping, and other large components that are radioactive to a comparable degree.''

The petition suggested that granting the petition would remove unnecessary burden from licensees who store major radioactive components on their sites during plant operations because they have limited operating funds and cannot use decommissioning funds for the disposal of these components.

The NRC published a notice of docketing and request for comment in the **Federal Register** on June 12, 2019 (84 FR 27209).

II. Public Comments on the Petition

A. Overview of Public Comments

The public comment period closed on August 26, 2019. The NRC received a total of six public comment submissions, with six unique comments from the general public and industry. Five commenters supported the petition and one commenter opposed the petition.

B. NRC Response to Public Comments

Comment: One commenter suggested an approach to allow the use of excess decommissioning trust funds for disposal of major radioactive components. In this approach, the NRC could allow operators to reallocate excess decommissioning trust funds for operational expenses through a two-step process: (1) Excess funds are identified and returned from holder; and (2) operator uses returned funds to manage operational expenses, including disposal of large components.

NRC Response: The process described in the comment is available now, upon request by a licensee through the exemption process (§ 50.12, ''Specific exemptions''), which requires a site-specific review and approval by the NRC. A projected excess in the decommissioning trust fund is one factor that the NRC would consider in reviewing an exemption request. Other potential factors include the size of the

excess compared to the site-specific cost estimate (SSCE), whether the expense is included in a SSCE, evidence that funds have been collected or set aside for the activity in a comingled decommissioning trust fund, and availability of rate collection as a means to resolve a shortfall in radiological decommissioning funding. Any decision on an exemption request to use decommissioning funds to dispose of major radioactive components during operation would be based on a totality of the information in the request and any other information of which the NRC is aware. It should be noted that cost estimates for decommissioning are less accurate the further out in time the plant is from decommissioning. Thus, a release of funds without NRC approval whenever an excess is identified by the licensee would diminish decommissioning funding assurance, even if the excess is identified by comparison to a SSCE. The NRC has previously addressed this issue in the denial of PRM–50–88 (73 FR 62220; October 20, 2008).

Comment: One commenter stated that operators are making a business decision to store large components during a plant's operational period and dispose of the major radioactive components with decommissioning trust funds once the decommissioning period begins, despite storage and monitoring costs. The commenter states that this results in a potential for loss of control of radiological material, if improperly stored/monitored.

NRC Response: Existing NRC regulations ensure adequate control of radiological material, including major radioactive components that have been removed from service. Proper storage and monitoring of radiological material is addressed through the NRC's onsite inspection procedures.

Comment: One commenter stated that the NRC should consider early use of decommissioning trust funds by licensees if the disposal costs are specifically included in the cost estimate. The commenter stated that this could be achieved either by the licensee preparing a SSCE that included the items for which excess funds are to be used, or by the NRC revising the generic formula for trust fund calculation to require additional funds to account for these waste volumes, effectively increasing the estimated waste volume factor of the formula. The commenter noted that a change to the generic formula in this manner is problematic because some basis would be required to account for later reducing the waste volume based on operational disposal activities, which may be an ongoing or repeated activity during the operational life of a facility.

NRC Response: The NRC agrees with the commenter that a revision to the § 50.75 Table of Minimum Amounts would be problematic. The formulas provided in this table are generic and designed to provide a reasonable estimate of radiological decommissioning costs for the facility. Revising the table to account for the disposal of major radioactive components prior to decommissioning is difficult due to several factors, including site-specific variations in the generation and disposal of these components. As such, the Table of Minimum Amounts has not been updated for over 30 years. However, the NRC is considering updates to the generic decommissioning funding formula to make it more reflective of current cost considerations as part of the proposed rule, ''Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning'' (RIN 3150–AJ59), and will seek public comment on the matter. Nonetheless, currently licensees can use the existing formula, or an SSCE, as part of a demonstration that excess funds exist in the decommissioning trust fund to support either an exemption request or for other purposes, such as the reallocation of other funds. Projected excess funds would be one factor the NRC would consider when reviewing an exemption request. The staff notes the determination of excess funds relies on long-term projections that may prove inaccurate because unpredictable changes in economic conditions could result in future shortfalls in the decommissioning trust fund. Therefore, in reviewing an exemption request, the NRC would consider the totality of information provided in the request and any other information of which the NRC is aware.

Comment: One commenter stated that an ''innovative financial approach'' that could provide for early removal of large parts would be the establishment by the NRC of a process whereby a licensee can have access to excess decommissioning trust funds (where ''excess'' should consider spent fuel management funds, whether comingled or not) that can only be used for specific purposes by the licensee, such as management of large component/operational wastes or other items that will contribute to the ultimate decommissioning of the facility.

NRC Response: Under the NRC's existing regulatory framework, licensees can request access to excess decommissioning funds on such a basis through the exemption process.

Comment: Three commenters stated that nuclear utilities should have the flexibility to use decommissioning trust fundsduring operations to facilitate the timely disposal of these components in acost-effectivemanner to maximize the reduction in disposal cost and therefore aid in ensuringthat ample decommissioning trust funds remain available when fulldecommissioning takes place.

NRC Response: If excess decommissioning trust funds are available (*e.g.,* as determined by comparing decommissioning fund growth against an SSCE), then licensees may use existing procedures to access the available funds. If excess funds are not available, then licensees may use operating revenues or continue to store the components on site until such time as either excess funds are available (and then request an exemption to use those funds) or until decommissioning begins.

Comment: Two commenters stated that the industry and NRC have experience with thedecommissioning of nuclear power plants and the time has come to modernize the decommissioning regulatory process.

NRC Response: The NRC is currently pursuing decommissioning improvements in a separate rulemaking, ''Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning'' (82 FR 13778).

III. Reasons for Denial

The NRC is denying the petition because a licensee may access the decommissioning trust fund to pay for the disposal of major radioactive components (1) by requesting reimbursement when submitting their decommissioning cost estimate per § 50.82 or (2) by requesting an exemption under § 50.12 to permit withdrawal from the decommissioning trust fund prior to decommissioning. Although the Commission has stated that trust fund withdrawals for disposal of major radioactive components would be granted only ''in extraordinary circumstances'' (73 FR 62222; October 20, 2008), the NRC reviews each exemption request based on the merit of the facts provided in the request.

While the petitioner noted that only ''excess'' funds would be used from the decommissioning trust fund to pay for the disposal of major radioactive components, the NRC notes that whether there is an excess would be based on economic projections. Economic projections are less accurate the further out in time they attempt to project, and, therefore, changes in economic conditions combined with

withdrawals from the decommissioning trust fund could potentially result in future shortfalls in the fund. Nevertheless, a projected excess is one factor that the NRC would consider in reviewing an exemption request. Other potential factors include: The size of the excess compared to the SSCE, whether the expense is included in a SSCE, evidence that funds have been collected or set aside for the activity in a comingled decommissioning trust fund, and availability of rate collection as a means to resolve a shortfall in radiological decommissioning funding. Any decision on an exemption request to use decommissioning funds to dispose of major radioactive components during operation would be based on a totality of the information in the request and any other information of which the NRC is aware. These circumstances are site-specific and dependent on the unique financial status of each licensee.

The staff believes it would be difficult to develop generally applicable requirements to address the use of decommissioning trust funds for this purpose and therefore, more efficient to review such requests on a case-by-case basis. Therefore, the staff considers an exemption to be an adequate means for licensees to request a withdrawal from their decommissioning trust fund for the disposal of major radioactive components. If the staff sees an increase in exemption requests to withdraw decommissioning funds prior to decommissioning, then the NRC could reconsider whether addressing the issue through rulemaking would reduce the need for exemptions and be more efficient for the agency. Such reconsideration will include any experience and insights the staff has gained in evaluating exemption requests at that time.

Additionally, some licensees successfully pursued reallocating funding streams that would otherwise have been added to their decommissioning trust fund by establishing ''sub-accounts'' in their decommissioning trust funds. Such sub-accounts are not regulated by the NRC and, therefore, can be used at the discretion of the licensee at any time during operations or decommissioning. For rate-regulated licensees, these sub-accounts are typically funded with Public Utility Commission-authorized rate collections once it is established that the trust dedicated to radiologically decommissioning is sufficiently funded in accordance with NRC regulations. While non-rate-regulated (*i.e.,* merchant) licensees do not have access to rate collection, they may still fund such sub-accounts through alternate means or request a reallocation of funds across their decommissioning trust fund accounts using the 10 CFR 50.12 exemption process. The NRC is denying the petition because it does not raise a significant safety or security concern and the requested amendments are not necessary to enable licensees to access excess decommissioning funding prior to decommissioning for the purpose of disposal of major radioactive components under existing regulations in 10 CFR part 50.

IV. Conclusion

For the reasons cited in this document, the NRC is denying PRM–50–119. The NRC reaffirms that its existing regulations continue to provide reasonable assurance of adequate protection of public health and safety.

Dated: January 24, 2022.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2022–01685 Filed 2–3–22; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 429 and 431

[EERE–2020–BT–TP–0011]

RIN 1904–AE62

Energy Conservation Program: Test Procedure for Electric Motors; Extension of Comment Period

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking; extension of public comment period.

SUMMARY: On December 17, 2021, the U.S. Department of Energy (''DOE'') published a notice of proposed rulemaking (''NOPR'') on potential amendments to its test procedure for electric motors. The NOPR provided an opportunity for submitting written comments, data, and information on the proposal by February 15, 2022. DOE received requests from the National Electrical Manufacturers Association (''NEMA'') and the Hydraulic Institute (''HI'') on January 25, 2022, and January 26, 2022, respectively, asking DOE to extend the public comment period for 30 additional days. DOE has reviewed these requests and is granting an extension of the public comment period to allow public comments to be submitted until February 28, 2022.

DATES: The comment period for the NOPR published on December 17, 2021 (86 FR 71710), is extended. DOE will accept comments, data, and information regarding this request for information (RFI) received no later than February 28, 2022.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2020–BT–TP–0011, by any of the following methods:

(1) *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

(2) *Email: ElecMotors2020TP0011@ee.doe.gov.* Include the docket number EERE–2020–BT–TP–0011 or regulatory information number (''RIN'') 1904–AE62 in the subject line of the message.

No telefacsimiles (''faxes'') will be accepted.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing COVID–19 pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket, 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, 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?D=EERE-2020-BT-TP-0011.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building

Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: On December 17, 2021, DOE published a NOPR proposing to amend the existing scope of the DOE test procedures for electric motors consistent with related industry changes for nomenclature and test procedure developments (*i.e.,* for air-over electric motors, submersible electric motors, electric motors greater than 500 horsepower, electric motors considered small, inverter-only electric motors, and synchronous electric motors); add test procedures, metric, and supporting definitions for additional electric motors covered under the proposed scope; and update references to industry standards to reference current versions. (86 FR 71710) Furthermore, DOE proposed to adopt industry provisions related to the prescribed test conditions to further ensure the comparability of testing. In addition, DOE proposed to update certain testing instructions to reduce manufacturer burden. Further, DOE proposed to amend the provisions pertaining to certification testing and determination of represented values for electric motors other than dedicated-purpose pool pump motors, apply these provisions to the additional electric motors proposed for inclusion in the scope of the test procedure, and to move both provisions consistent with the location of other certification requirements for other covered products and equipment. Finally, DOE proposed to add provisions pertaining to certification testing and determination of represented values for dedicated-purpose pool pump motors. DOE is seeking comment from interested parties on these proposals.

Interested parties in the matter, NEMA (on January 25, 2022) and the Hydraulic Institute (on January 26, 2022) requested an extension of the public comment period for 30 additional days (NEMA, No. 9 at p. 1; HI, No. 11 at p.1).[1] NEMA commented that the extension is necessary due to delays in developing their responses given the proposed scope of products along with the extent of information to be gathered. HI commented more time is needed for the pump industry to review and provide comment relating to the testing of submersible motors.

DOE has reviewed the requests and is extending the comment period to allow additional time for interested parties to submit comments. The proposed rule was published in the **Federal Register** on December 17, 2021, and a 60-day comment period was provided from the date of publication. In light of the submitted requests, DOE believes that additional time is warranted, and that extending the comment period until the end of the month of February is sufficient. Therefore, DOE is extending the comment period until February 28, 2022.

Signing Authority

This document of the Department of Energy was signed on January 28, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 31, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–02281 Filed 2–3–22; 8:45 am]

BILLING CODE 6450–01–P

[1] The parenthetical reference provides a reference for information located in DOE's rulemaking docket. (Docket No. EERE–2020–BT–TP–0011, which is maintained at *www.regulations.gov/#!docketDetail;D=EERE-2020-BT-TP-0011*). The references are arranged as follows: (Commenter name, comment docket ID number, page of that document).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 27

[Docket No. FAA–2021–0943; Special Conditions No. 27–21–01–SC]

Special Conditions: Robinson Helicopter Company Model R66 Helicopter; Pressure Refueling Provisions

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for the Robinson Helicopter Company (RHC) Model R66 helicopter. This helicopter will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for normal category helicopters. This design feature is a pressure refueling system. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Send comments on or before March 7, 2022.

ADDRESSES: Send comments identified by Docket No. FAA–2021–0943 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC, 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in title 14, Code of Federal Regulations (14 CFR) 11.35, the FAA will post all comments received without change to *http://www.regulations.gov/,* including any personal information you provide. The

FAA will also post a report summarizing each substantive verbal contact received about these special conditions.

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 these special conditions contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to these special conditions, 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 the indicated comments will not be placed in the public docket of these special conditions. Submissions containing CBI should be sent to Monica Abboud, Propulsion Section, AIR–794, Los Angeles ACO Branch, Aircraft Certification Service, Federal Aviation Administration, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (562) 627–5223; email *monica.m.abboud@faa.gov.* Comments the FAA receives, which are not specifically designated as CBI, will be placed in the public docket for these special conditions.

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Monica Abboud, Propulsion Section, AIR–794, Los Angeles ACO Branch, Aircraft Certification Service, Federal Aviation Administration, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (562) 627–5223; email *monica.m.abboud@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

The FAA will consider all comments received by the closing date for comments. The FAA may change these special conditions based on the comments received.

Background

On July 15, 2021, RHC applied for a change to Type Certificate No. R00015LA for the Model R66 helicopter. This change incorporated a pressure fueling system in the Model R66 helicopter. The RHC Model R66 helicopter, which is a derivative of the earlier models of the Model R66 helicopter currently approved under Type Certificate No. R00015LA, is a part 27 normal category helicopter. It is a single turbine engine helicopter with a four-passenger maximum passenger capacity and has a maximum gross weight, with no external load, of up to 2,700 pounds depending on the model configuration.

Type Certification Basis

Under the provisions of 14 CFR 21.101, RHC must show that the Model R66 helicopter, as changed, continues to meet the applicable provisions of the regulations listed in Type Certificate No. R00015LA or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*e.g.,* 14 CFR part 27) do not contain adequate or appropriate safety standards for the RHC Model R66 helicopter because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the RHC Model R66 helicopter must comply with the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Feature

The RHC Model R66 helicopter will incorporate the following novel or unusual design feature:

A pressure refueling system, which will allow for optional pressure fueling.

Discussion

RHC proposes to modify the Model R66 helicopter by incorporating a pressure refueling system that would allow for optional pressure fueling from a fueling port on the right side of the fuselage and the existing gravity system via the fuel filler cap on top of the main fuel tank. This modification would provide faster, easier, and safer refueling when the engines are running and rotors turning compared to the existing fueling system located on the top of the main fuel tank. The pressure refueling system cannot be used for defueling and would include a crash-resistant fuel hose that runs from the fueling port on the right side to an inlet at the top of the fuel tank on the left side of the helicopter.

Part 27 does not contain requirements for pressure refueling for normal category helicopters. However, 14 CFR 29.979, amendment 29–12, effective February 1, 1977, provides these requirements for transport category helicopters. Accordingly, these proposed special conditions are based on § 29.979 to provide requirements for the inclusion of the optional pressure refueling system on the Model R66 helicopters. 14 CFR 29.979 includes standards for pressure refueling and fueling provisions below fuel level on transport category rotorcraft.

This regulation is intended to prevent hazards to ground crew, flight crew, and occupants by reducing the probability of exposure to hazardous quantities of fuel due to spillage and ensuring the pressure refueling/defueling system is designed to prevent overfilling the fuel tank and to withstand an ultimate load overpressure event without failure.

Section 29.979(a) requires each fueling connection below the fuel level in each tank have a means to prevent the escape of hazardous quantities of fuel from that tank in case of malfunction of the fuel entry valve.

Section 29.979(b) requires systems intended for pressure refueling have a means in addition to the normal means for limiting the tank content to prevent damage to the tank in case of failure of the normal means.

Section 29.979(c) requires the rotorcraft pressure fueling system (not fuel tanks and fuel tank vents) to withstand an ultimate load that is 2.0 times the load arising from the maximum pressure, including surge,

that is likely to occur during fueling. The maximum surge pressure must be established with any combination of tank valves being either intentionally or inadvertently closed.

Section 29.979(d) requires the rotorcraft defueling system (not including fuel tanks and fuel tank vents) to withstand an ultimate load that is 2.0 times the load arising from the maximum permissible defueling pressure (positive or negative) at the rotorcraft fueling connection. The design proposed by RHC does not include defueling capability.

The proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

These special conditions are applicable to the RHC Model R66 helicopter. Should RHC apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on one model of helicopter. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 27

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Robinson Helicopter Company Model R66 helicopters.

The pressure refueling system must be designed and installed as follows:

(a) Each fueling connection below the fuel level in each tank must have the means to prevent the escape of hazardous quantities of fuel from that tank in case of malfunction of the fuel entry valve.

(b) For systems intended for pressure refueling, a means in addition to the normal means for limiting the tank content must be installed to prevent damage to the fuel tank in case of failure of the normal means.

(c) The rotorcraft pressure fueling system (not fuel tanks and fuel tank vents) must withstand an ultimate load that is 2.0 times the load arising from maximum pressure, including a surge, that is likely to occur during fueling. The maximum surge pressure must be established with any combination of tank valves being either intentionally or inadvertently closed.

Issued in Kansas City, Missouri, on February 1, 2022.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2022–02387 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0028; Airspace Docket No. 21–ASO–41]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Dyersburg, TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E surface airspace in Dyersburg, TN, as the Nally Dunston non-directional beacon (NDB) has been decommissioned, and associated approaches cancelled for Dyersburg Regional Airport. This action would update the airport name and geographic coordinates. In addition, this action would also make an editorial change replacing the term Airport/Facility Directory with the term Chart Supplement in the legal description of associated Class E airspace. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before March 21, 2022.

ADDRESSES: Send comments on this proposal to: The United States Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2021–0028; Airspace Docket No. 21–ASO–41 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F Airspace Designations and Reporting Points and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: 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 would amend airspace in Dyersburg, TN, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on 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 (Docket No. FAA–2021–0028 and Airspace Docket No. 21–ASO–41) and be submitted in triplicate to DOT Docket Operations (see

ADDRESSES section for the address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–0028; Airspace Docket No. 21–ASO–41.'' 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 document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class E surface airspace at Dyersburg Regional Airport, Dyersburg, TN, due the decommissioning of the Nally Dunston NDB and cancellation of associated approaches. This action would also update the airport name (formerly Dyersburg Municipal Airport) and geographic coordinates to coincide with the FAA's database.

This action would also replace the outdated term Airport/Facility Directory with the term Chart Supplement in the airport description.

Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Class E airspace designations are published in Paragraph 6002 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would 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 proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11F, Airspace Designations, and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6002 Class E Surface Airspace.

* * * * *

ASO TN E2 Dyersburg, TN [Amended]

Dyersburg Regional Airport, TN
(Lat. 35°59′53″ N, long. 89°24′24″ W)

That airspace upward from the surface within a 4.7-mile radius of the Dyersburg Regional Airport. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Issued in College Park, Georgia, on January 27, 2022.

Andreese C. Davis,

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

[FR Doc. 2022–02342 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Census Bureau

15 CFR Part 30

[Docket Number 220124–0033]

RIN 0607–AA58

Foreign Trade Regulations (FTR): Electronic Export Information (EEI) Filing Requirements for Shipments Between the United States and Puerto Rico and the U.S. Virgin Islands (USVI)

AGENCY: Census Bureau, Commerce Department.

ACTION: Advance Notice of Proposed Rulemaking; withdrawal.

SUMMARY: The Census Bureau published an Advance Notice of Proposed Rule Making (ANPRM) in the **Federal Register** on September 17, 2020 to request comments on the overall impact of the removal of the Electronic Export Information (EEI) filing requirements for shipments between the United States, Puerto Rico and the U.S. Virgin Islands. The Census Bureau has decided to continue the current EEI filing requirement for Puerto Rico and the USVI and continue to publish the U.S. Trade with Puerto Rico and U.S. Possessions (FT–895) Publication Series. This decision was made after careful consideration based on the feedback received from the ANPRM and discussions between the Census Bureau and several stakeholders. The Census Bureau will continue to collect the EEI because there is no alternative data source that yields the same high-quality data for Puerto Rico and the U.S. Virgin Islands. The EEI data meets the Census Bureau's statistical objectives and the needs of its data users, including the Bureau of Economic Analysis (BEA), who produces the Gross Domestic Product estimates for Puerto Rico and the U.S. Virgin Islands, which is a Principal Federal Economic Indicator. Both the Census Bureau and BEA are open to considering proposed alternative data sources which will be evaluated, tested, and verified to determine whether the data meet the statistical objectives of the current EEI.

FOR FURTHER INFORMATION CONTACT: Lisa E. Donaldson, Division Chief, Economic Management Division (EMD), Census Bureau, by phone (301) 763–7296 or by email at *lisa.e.donaldson@census.gov* or Kiesha Downs, Chief, Trade Regulations Branch, EMD, Census Bureau, by phone (301) 763–7079 or by email at *kiesha.downs@census.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Census Bureau is responsible for collecting, compiling, and publishing export trade statistics for the United States under the provisions of Title 13, United States Code (U.S.C.), Chapter 9, Section 301. Collecting and compiling trade statistics between the United States, Puerto Rico, and other territories is part of the U.S. Census Bureau's monthly processing of EEI. Ultimately, these statistics are sourced from the EEI filings in the Automated Export System (AES) and published in the FT–895 Publication Series. This FT–895 monthly program presents total quantity and value of detailed commodities shipped between the United States, Puerto Rico, and U.S. territories, including the U.S. Virgin Islands (USVI).

The ANPRM published in the **Federal Register** on September 17, 2020, (85 FR 58016) received 93 comments on the overall impact of the removal of the EEI filing requirements for shipments between the United States, Puerto Rico and the USVI. The Census Bureau received 50 comments in support of maintaining the current EEI filing requirement and 43 comments supporting the removal of the EEI filing requirement. A summary of the comments is provided below.

Comments provided in support of removing the EEI filing requirement to Puerto Rico and the USVI fell under the following themes:

1. *Inequality:* Several commenters support removing the EEI filing requirement were concerned about unfair treatment of U.S. territories. While Puerto Rico and the USVI are not states, they are territories of the United States and exports to and from these territories are considered domestic, not international shipments. Several commenters believe federal agencies should employ consistent treatment of Puerto Rico and the USVI for statistical data. Another commenter indicated, other agencies under the Department of Commerce (DOC), such as the Bureau of Industry and Security (BIS) and the International Trade Administration do not treat shipments to and from Puerto Rico and the USVI as exports. Another commenter stated that the requirement of EEI is the reason many businesses deny service to the trade community located in U.S. Caribbean territories. Another commenter indicated the EEI filing requirement hinders trade competitiveness and negatively impacts job creation.

2. *Increased cost and burden:* Several commenters were concerned that requiring EEI filing to U.S. territories has increased the cost and time of the shipping process for U.S. exporters and freight forwarders. Some commenters indicate the need to dedicate staff and/or hire additional personnel to manage EEI filings has increased labor cost for businesses. Commenters were also concerned that the requirement to file EEI between the mainland U.S., Puerto Rico and the USVI imposes substantial regulatory and economic burden on exporters. Several commenters stated that the Department of Commerce should minimize any governmental paperwork burden (electronic or otherwise) on U.S. citizens engaged in lawful commercial transactions within the U.S. Several commenters also indicated the EEI filing process imposes unnecessary burden on commerce by impeding the flow of trade and economic development in these territories due to the additional paperwork and administrative costs imposed by the EEI filing requirement. Several commenters stated that the costs are significant in terms of time lost, human resources required; many shippers and manufacturers in the U.S. have decided not to ship to these territories due to these additional steps in the shipping process and restrictions on trade. Additionally, some commenters pointed out that the cost of the EEI filing limits sourcing of U.S. products and increases the cost of goods in Puerto Rico and the USVI.

3. *Possible alternative data sets:* Several commenters identified the possibility of alternative methods for collecting export statistics data. One commenter stated that Puerto Rico is a part of the same U.S. Customs system and should use the same data collection methods as the other 50 states. Other commenters suggested that EEI is viable through data that already exists from multiple sources. One commenter suggested that EEI filing is repetitive and duplicative to manifest requirements of other agencies. Several commenters suggested specific alternative data sets such as the DOC's Bureau of Economic Analysis (BEA) data, which collects trade data that is used to calculate U.S. Gross Domestic Product (GDP) activity, state-to-state activity, and U.S. international transactions. Several commenters also proposed the use of Customs and Border Protection (CBP) manifest data, Puerto Rico's Sistema Unificado de Rentas Internas (SURI), Puerto Rico Port Authority data, monthly reporting similar to the current pipeline reporting, and the FT–895 report as alternative data sources.

Comments provided for maintaining the EEI filing requirement to Puerto Rico and USVI fell under the following themes:

1. *Statistical purposes:* The EEI reporting requirement yields high quality data for Puerto Rico and the USVI that serve several specific statistical objectives. Eliminating the mandatory requirement would remove an additional step in the shipping process. However, there would be several statistical implications associated with this change. Statistical data provides insight on policy decisions, GDP estimates, business development and marketing, economic recovery, research and academia as well as historical data and methodology, critical in measuring economic growth for Puerto Rico and the USVI.

A. *Public Policy Decisions:* Several commenters noted, EEI is utilized by the Government of Puerto Rico to produce statistical reports, gauge economic activity, and assist in sound policy making. A federal agency commented that it uses the data in its initiative to estimate Puerto Rico GDP statistics. Specifically, the agency commented that reliable GDP statistics for U.S. territories contribute to a better understanding of economic development, such as the impact of federal disaster relief spending in these areas. For example, to date, Congress has appropriated more than $60 billion for Puerto Rico recovery efforts following hurricanes in 2017 and earthquakes in 2020. Without high-quality GDP statistics, it is difficult for policy makers to gauge the impact of such funding on the Puerto Rican economy. Additionally, another federal agency has concerns about the loss of data, specifically, petroleum trade between the United States and Puerto Rico. This federal agency uses the data for calculation of the total shipped volumes of petroleum and other fuels. There is currently no other source of information or method for tracking trade flows of oil and other energy-related commodities between the United States and Puerto Rico. There is no alternative data source to collect this information because Puerto Rico does not locally collect the data and these data are not included in any other U.S. Census Bureau economic surveys. Commenters are concerned because this information can aid federal agencies in developing strategic plans to ensure Puerto Rico has resilient power generation systems for the future, as the current Administration starts to steer away from oil and towards sustainable energy and information.

B. *Business Development and Marketing:* One commenter stated that accurate and precise data is critical for the development of small businesses in Puerto Rico and to develop and update business and marketing plans to move Puerto Rico's economy forward. Another commenter noted that businesses in these territories and the U.S. mainland use this detailed data to inform choices and services around new and existing markets, which allows for more competition and better consumer options.

C. *Economic Recovery:* Several commenters noted, keeping the EEI filing requirement for Puerto Rico and the USVI allows these territories to rebuild their economies and accurately measure, project, and plan economic development. One commenter noted, the lack of reliable statistics is the worst scenario for a country in economic crisis as they work towards restructuring their debt and attaining a sustainable economy. Several other commenters noted that without a viable and tested alternative data source, the proposal to remove the requirements will make it impossible to measure and analyze Puerto Rico's economy. Other commenters noted that an economic development plan is urgent, and it cannot be attained without having complete, accurate and confident data that includes the information for shipments between the United States and Puerto Rico and USVI.

D. *Research and Academic Importance:* Several commenters were concerned that the proposed rule to eliminate the EEI filing requirement to Puerto Rico and the USVI will have a significant impact on research and academia. Commenters noted that without the filing requirement, economic students, scholars, entrepreneurs and citizens will not be able to access updated Census Bureau data for research policy purposes. One scholar specifically noted that the Census Bureau's statistical information for economic and agricultural economic courses is useful to students completing projects and thesis papers within their master's program. Another commenter was also concerned that the loss of this data will directly impact the agricultural industry with current global economic and climatic change.

2. *Enforcement Purposes:* We received several comments against removing the EEI filing requirement for export control and enforcement purposes. One commenter noted that without the collection of data from the U.S. mainland to Puerto Rico and USVI, enforcement agencies lose visibility on potential criminal activity. The Census Bureau consulted with one federal agency on this comment. This agency noted that the removal of the EEI filing requirements for shipments from the U.S. to those territories would adversely impact the agency's ability to ensure the effective enforcement of items subject to the Export Administration Regulations, potentially diverted to foreign countries.

3. *No valid alternative data set:* Though commenters presented potential alternative data sets, one commenter noted that the level of detail would not be similar to that obtained through the EEI requirement, and the data would not be compiled with the rigorousness as that by the Census Bureau. One federal agency also noted that the EEI is high-quality economic data which is not typical for the U.S. territories because the U.S. territories are not included in most federal surveys. Territory-level surveys and administrative data are limited. Several commenters noted, there is currently no substitute for EEI that is routinely available, continuous, current, high frequency and published with documentation and technical support. Without an alternative data source that meets the same statistical objectives, it is not possible to continue to produce GDP estimates for Puerto Rico or the USVI. Should the broader FT–895 report be eliminated as a result of the discontinuation of the EEI-sourced data, GDP estimates for the territory of American Samoa will also be at risk.

4. *Cost Benefit:* Several commenters noted that the Automated Export System (AES) is a mature system the trade industry understands and knows how to operate. There is concern that creating an entirely new system to capture the same data in today's current environment is an unnecessary burden. Additionally, creating a new system would come at a significant cost to the U.S. Government during a time of increased strain on Government funding, as well as costs to the industry. One commenter noted that many EEI filers for Puerto Rico's data also use the AES for international shipments to foreign countries and adding an alternative system would add a burden to their current operations and workflow. Several economists commented that the requirement to file EEI does not add significant burden on business and the cost and value of the EEI data is greater than the inconvenience to the trade compared to the potential sales acquired, the current information technologies and the fact that the bulk of the shipments to the U.S. are done by large U.S. corporations.

5. *GDP Estimates:* Several commenters noted that the Census Bureau's FT–895 reports and other statistical trade documents provide routine, consistent, and continuous monthly and annual data that is necessary and relevant for statistical and time-series compatibility. These commenters also added that consistent definitions are critical to ensure GDP estimates and the loss of the FT–895 and EEI reporting will adversely affect the computations of GDP estimates. One commenter specifically stated that the methodology should include a monthly total of the value of goods between the U.S., Puerto Rico and the USVI rather than presenting it on an annual frequency. Another commenter who has used the data for many years is concerned that interruptions or inconsistencies with the current dissemination of the Census Bureau data would create problems. Additionally, one federal agency noted that they significantly rely on trade data

from the FT–895 in constructing reliable and consistent economic statistics, including GDP for U.S. territories. Such statistics provide key insight into the territorial economies, and meaningful information to businesses and decision makers alike. Territorial GDP are highly reliant on export and import data provided from the Census Bureau's FT–895. The direct concern is that an elimination of EEI reporting requirements could directly impact the availability of import data used in the USVI GDP statistics. To illustrate the significance of this information loss, in 2018 exports reported in the FT–895 accounted for 59-percent and 9-percent of American Samoa and the USVI GDP, respectively. The direct and indirect impact associated to the elimination of the EEI reporting requirements could severely affect the usefulness of American Samoa, Northern Mariana Islands, Guam and USVI GDP as time series statistics. Should the reporting requirement be eliminated, it remains unclear if the Census Bureau will continue to make non-EEI-sourced trade data available for these territories. Other commenters stated that the lack of data with no other avenue for gathering the information would be harmful and unfortunate if such a longtime source of information were to disappear. Similarly, a commenter noted that the FT–895 constitutes an excellent and unique tool benefitting individuals, businesses, academia, etc. and for which there is no viable substitute available.

Robert L. Santos, Director, Census Bureau, approved the publication of this notice of proposed rulemaking in the **Federal Register**.

Dated: January 31, 2022.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–02341 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. FDA–2020–N–1819]

RIN 0910–AH56

Certain Requirements Regarding Prescription Drug Marketing

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend certain prescription drug marketing regulations to reflect changes to affected provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) resulting from enactment of the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act (DQSA). This action, if finalized, will remove or revise outdated and conflicting regulatory requirements to align with changes to affected provisions of the FD&C Act following enactment of the DSCSA.

DATES: Submit either electronic or written comments on the proposed rule by April 5, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 5, 2022. Electronic comments must be submitted on or before that date. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1819 for ''Certain Requirements Regarding Prescription Drug Marketing.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly available at *https://www.regulations.gov,* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments

received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Center for Drug Evaluation and Research, Office of Compliance, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3130, *WDD3PLrequirements@fda.hhs.gov*.

With regard to biologics: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to amend part 203 (21 CFR part 203) to reflect changes to affected provisions of the FD&C Act following enactment of the DSCSA, Title II of the DQSA (Pub. L. 113–54). In this proposed rulemaking, we are proposing to amend certain provisions of part 203 to avoid potential confusion with the new standards and requirements for wholesale distributors applicable under the FD&C Act (as amended by the DSCSA), and to make certain related, conforming changes.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would: (1) Modify the ''scope'' and ''purpose'' sections of the regulations in part 203 to eliminate references to wholesale distribution, (2) delete Subpart E—Wholesale Distribution in its entirety, (3) delete from § 203.3 the definitions for terms that only appeared in subpart E, and (4) modify other provisions of part 203 to eliminate references to wholesale distribution to conform to the changes described above.

C. Legal Authority

We are issuing this proposed rule under sections 503(c), 503(e), 582, 583 and 701(a) of the FD&C Act (21 U.S.C. 353(c), 353(e), 360eee-1, 360eee-2, and 371(a)).

D. Costs and Benefits

This proposed rule is a companion to the proposed rule ''National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers'' (licensing standards proposed rule) which implements the national licensing standards requirements of DSCSA. The licensing standards proposed rule, which would amend part 205, is published elsewhere in this issue of the **Federal Register**. We analyze the effects of the two rules together; thus, we include the benefits and costs of this proposed rule in the regulatory impact analysis of the licensing standards proposed rule.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
CFR	Code of Federal Regulations.
DSCSA	Drug Supply Chain Security Act.
DQSA	Drug Quality and Security Act.
FDA or the Agency.	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
U.S.C.	United States Code.

III. Background

A. Introduction

The DQSA was enacted on November 27, 2013. The DQSA contains two titles: Title I, the Compounding Quality Act and Title II, the DSCSA. The DSCSA amended Chapter V of the FD&C Act by adding Subchapter H (Pharmaceutical Distribution Supply Chain), which includes new sections 581 through 585 (21 U.S.C. 360eee through 360eee–4), and by amending section 503(e) of the FD&C Act. As amended, section 503(e) of the FD&C Act, together with new section 583 of the FD&C Act, require the Secretary of Health and Human Services (Secretary) [1] to establish national prescription drug wholesale distributor licensure standards. In addition, section 582 of the FD&C Act establishes prescription drug product tracing requirements for wholesale distributors and their trading partners. FDA is proposing to revise the regulations in part 203 by removing or amending those sections of the regulations that have been affected by the changes to the FD&C Act through the enactment of the DSCSA.

[1] This function has been delegated to FDA.

B. Need for the Regulation

This rulemaking, when finalized, would: (1) Remove existing regulations regarding wholesale distribution of prescription drugs that conflict with or were superseded by new requirements established under the DSCSA; (2) modify other existing regulations for consistency with the regulations on standards for licensure of wholesale distributors that FDA is proposing pursuant to section 583 of the FD&C Act; and (3) make certain related, conforming changes. This rulemaking is needed to remove outdated regulations and to prevent confusion about requirements for wholesale distributors under the FD&C Act.

IV. Legal Authority

The Agency is proposing this rule under the authority to impose requirements regarding prescription drug marketing and wholesale drug distribution granted to it under various sections of the FD&C Act, including sections 503(c), 503(e), 582, 583, and 701(a). Section 503(c) describes certain restrictions on prescription drug marketing, including relating to the sale of drug samples and of drugs that have been purchased by hospitals or other healthcare entities. Section 503(e), together with section 583 of the FD&C Act, require the Secretary to establish national prescription drug wholesale distributor licensure standards, while section 582 describes requirements applicable to wholesale distributors and other entities related to product tracing. Section 701(a) provides general authority to issue regulations for the efficient enforcement of the FD&C Act. By clarifying provisions related to prescription drug marketing and by removing provisions relating to wholesale distribution, this rule, when finalized, is expected to aid in the efficient enforcement of the FD&C Act.

V. Description of the Proposed Rule

This proposed rule would make the deletions and changes to the existing regulations in part 203 discussed below as well as technical changes for clarity.

1. Scope and Purpose (§§ 203.1 and 203.2)

Existing §§ 203.1 and 203.2 describe the scope and purpose of the regulations in part 203, respectively. The proposed revisions would narrow the scope and purpose descriptions in light of the proposed elimination of requirements relating to wholesale distributors from part 203. We plan to address the standards and requirements related to wholesale distributor licensing elsewhere in our regulations, in accordance with the applicable provisions of the FD&C Act (as amended by the DSCSA).

2. Definitions (§ 203.3)

Certain definitions that currently appear in this section would be modified or eliminated.

a. Authorized distributor of record. The amendments to section 503(e) effectuated by the DSCSA eliminated the definition of ''authorized distributors of record'' from section 503(e) of the FD&C Act, which previously provided that the definition applied for the purposes of section 503(d) and 503(e). However, the DSCSA added a definition of the same term in section 503(d) of the FD&C Act, which relates to drug sample distribution, in section 503(d)(4). The ''authorized distributor of record'' definition in § 203.3 would be revised to reflect the fact that, as used in the amended part 203, the phrase would relate solely to distribution of drug samples. The revised ''authorized distributor of record'' definition would be found in the new § 203.3(a). In addition, as further discussed below, references to distribution of products by authorized distributors of record would be amended throughout the text of part 203, where appropriate, to clarify that these references relate only to distribution of drug samples.

b. Emergency medical reasons. The proposed rule would amend the definition of ''emergency medical reasons'' in the new § 203.3(l). Section 203.22, which sets forth exemptions from the sales restrictions described in § 203.20, generally provides an exemption from those restrictions for sales, purchases, or trades of a drug for emergency medical reasons (§ 203.22(d)). Section 203.3(m) currently states, in part, that ''emergency medical reasons'' include, but are not limited to, transfers of a prescription drug between healthcare entities or from a healthcare entity to a retail pharmacy *to alleviate a temporary shortage* of a prescription drug arising from delays in or interruption of regular distribution schedules, as well as transfers of prescription drugs by a retail pharmacy to another retail pharmacy *to alleviate a temporary shortage.* As a result, under § 203.22(d) such transfers to alleviate temporary shortages are exempt from the sales restrictions set forth in § 203.20. Certain of those transfers may, however, constitute ''wholesale distribution'' as defined in the DSCSA (section 503(e)(4) of the FD&C Act) because, while the ''wholesale distribution'' definition generally excludes distributions for ''emergency medical reasons,'' it states that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason. With certain exceptions, a person cannot simultaneously be a healthcare entity and a wholesale distributor (see § 203.3(p)). Because of this, FDA proposes to amend relevant language in the ''emergency medical reasons'' definition to clarify the relationship between it and the definition of ''wholesale distribution'' in section 503(e)(4) of the FD&C Act. In particular, we would add text to § 203.3(l) to make clear that a transfer made to alleviate a temporary shortage would generally be considered to be for ''emergency medical reasons'' for purposes of part 203 only where the transfer was either to fulfill a specific patient need or where the shortage was caused by a public health emergency (that is, where such transfers would not constitute ''wholesale distribution'' as defined in section 503(e)(4) of the FD&C Act). As explained in our companion proposed rulemaking for part 205 (21 CFR part 205), the Agency considers the transfer or sale of a drug from one dispenser to another dispenser made to fulfill a specific patient need to be outside the scope of the ''wholesale distribution'' definition in section 503(e)(4) of the FD&C Act.

c. Unauthorized distributor and wholesale distribution. The definitions of ''unauthorized distributor'' and ''wholesale distribution,'' currently codified in § 203.3(bb) and (cc), respectively, would be eliminated from part 203, because these terms would no longer appear in part 203, as amended. The definition of the term ''wholesale distributor'' would be modified to indicate that the term would have the meaning set forth in section 581(29) of the FD&C Act.

3. Exclusions (§ 203.22(h) and (i))

Paragraphs (h) and (i) of § 203.22, which set forth exemptions from the sales restrictions in § 203.20, would be modified to eliminate the phrase indicating that the applicable requirements for a wholesale distributor or retail pharmacy are contained in part 203, because FDA is proposing to remove § 203.50, as discussed in section V.5.

4. Subpart D—Samples

FDA would replace the term ''distributor'' where it appears in subpart D with the phrase ''authorized distributor of record'' where that phrase is not already used (§§ 203.30, 203.31, 203.34, 203.36, and 203.37). As noted above, the DSCSA added a definition of ''authorized distributors of record'' in section 503(d) of the FD&C Act, which relates to drug sample distribution.

5. Subpart E—Wholesale Distribution

FDA proposes to remove § 203.50 (Subpart E—Wholesale Distribution) in its entirety. On July 14, 2011, FDA proposed to remove § 203.50(a) (76 FR 41434). Before that rulemaking was finalized, the DSCSA was enacted. The DSCSA replaced section 503(e)(1)–(3) of the FD&C Act and added additional and different requirements for wholesale distributors. The DSCSA also added new requirements for wholesale distributors, including phased-in prescription drug tracing requirements in section 582(c) of the FD&C Act. FDA is withdrawing the above referenced July 14, 2011, proposed rule in a document published elsewhere in this issue of the **Federal Register**. In accordance with the changes in statutory authorities, FDA proposes to remove § 203.50 in its entirety. FDA is proposing new requirements for wholesale distributors and wholesale distribution consistent with the relevant provisions of the DSCSA in a separate proposed rulemaking for part 205, also published in this issue of the **Federal Register**.

VI. Proposed Effective Date

This regulation, if finalized as proposed, will be effective 30 calendar days after the date the final rule publishes in the **Federal Register**.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health

and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule imposes only minimal one-time costs of less than $100 per entity to read and understand the rule on small entities, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

We include the costs to read and understand this proposed rule in the regulatory impact analysis of the companion licensing standards proposed rule. The full preliminary analysis of economic impacts of both rules is available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* under ''National Standards for Licensing of Prescription Drug Wholesale Distributor and Third Party Logistics Providers'' (Ref. 1).

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30 that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov*. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Certain Requirements Regarding Prescription Drug Marketing; Proposed Rule, available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 203 be amended as follows:

PART 203—PRESCRIPTION DRUG MARKETING

■ 1. The authority citation for part 203 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

■ 2. In part 203, remove the words ''the act'' wherever they appear and add in their place ''the Federal Food, Drug, and Cosmetic Act''.

■ 3. Revise § 203.1 to read as follows:

§ 203.1 Scope.

This part sets forth procedures and requirements pertaining to the reimportation of prescription drugs, including both bulk drug substances and finished dosage forms; the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs, including bulk drug substances, that were purchased by hospitals or healthcare entities, or donated to charitable organizations; and the distribution of prescription drug samples. For purposes of this part, the term ''prescription drug'' has the meaning set forth in § 203.3(x).

■ 4. Revise § 203.2 to read as follows:

§ 203.2 Purpose.

The purpose of this part is to protect the public against drug diversion and enhance the security of the drug supply chain by establishing procedures and requirements relating to the reimportation of prescription drugs, the distribution of prescription drug samples, and the sale, purchase, or trade of prescription drugs purchased by hospitals or healthcare entities or donated to charitable organizations.

■ 5. Revise § 203.3 to read as follows:

§ 203.3 Definitions.

(a) *Authorized distributor of record* means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's drug samples.

(b) *Blood* means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(c) *Blood component* means that part of a single-donor unit of blood separated by physical or mechanical means.

(d) *Bulk drug substance* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(e) *Charitable institution* or *charitable organization* means a nonprofit hospital, healthcare entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.

(f) *Common control* means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

(g) *Distribute* means to sell, offer to sell, deliver, or offer to deliver a drug to a recipient, except that the term ''distribute'' does not include:

(1) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or

(2) Providing of a drug sample to a patient by:

(i) A practitioner licensed to prescribe such drug;

(ii) A healthcare professional acting at the direction and under the supervision of such a practitioner; or

(iii) The pharmacy of a hospital or of another healthcare entity that is acting at the direction of such a practitioner and that received such sample in accordance with the Federal Food, Drug, and Cosmetic Act and the regulations in this part.

(h) *Drug sample* means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(i) *Drug coupon* means a form that may be redeemed, at no cost or at reduced cost, for a drug that is prescribed in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(j) *Electronic record* means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

(k) *Electronic signature* means any computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

(l) *Emergency medical reasons* include, but are not limited to:

(1) Transfers of a prescription drug between healthcare entities or from a healthcare entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules, provided that such transfers are made in order to fulfill a specific patient need or respond to a public health emergency;

(2) Sales to nearby emergency medical services, *i.e.,* ambulance companies, police, and fire-fighting organizations in the same State or same marketing or service area, or nearby licensed practitioners, of drugs for use in the treatment of acutely ill or injured persons;

(3) Provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and

(4) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, provided that such transfers are made in order to fulfill a specific patient need or respond to a public health emergency but do not include regular and systematic sales to licensed practitioners of prescription drugs that will be used for routine office procedures.

(m) *FDA* means the U.S. Food and Drug Administration.

(n) *Group purchasing organization* means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and healthcare entities bound by written contract with the entity.

(o) *Handwritten signature* means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(p) *Healthcare entity* means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. Except as provided in § 203.22(h) and (i), a person cannot simultaneously be a ''healthcare entity'' and a retail pharmacy or wholesale distributor.

(q) *Licensed practitioner* means any person licensed or authorized by State law to prescribe drugs.

(r) *Manufacturer* means any person who is a manufacturer as defined by § 201.1 of this chapter.

(s) *Nonprofit affiliate* means any not-for-profit organization that is either associated with or a subsidiary of a charitable organization as defined in section 501(c)(3) of the Internal Revenue Code of 1954.

(t) *Ongoing relationship* means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's drug samples for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire drug sample line, the agreement must identify the specific drug samples that the distributor is authorized to distribute.

(u) *PDA* means the Prescription Drug Amendments of 1992.

(v) *PDMA* means the Prescription Drug Marketing Act of 1987.

(w) *Person* includes any individual, partnership, corporation, or association.

(x) *Prescription drug* means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(y) *Representative* means an employee or agent of a drug manufacturer or authorized distributor of record who promotes the sale of prescription drugs to licensed practitioners and who may solicit or receive written requests for the delivery of drug samples. A detailer is a representative.

(z) *Sample unit* means a packet, card, blister pack, bottle, container, or other single package comprised of one or more dosage units of a prescription drug sample, intended by the manufacturer or authorized distributor of record to be provided by a licensed practitioner to a patient in an unbroken or unopened condition.

(aa) *Wholesale distributor* has the meaning set forth in section 581(29) of the Federal Food, Drug, and Cosmetic Act.

■ 6. In § 203.22, revise paragraphs (h) and (i) to read as follows:

§ 203.22 Exclusions.

* * * * *

(h) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a registered blood establishment that qualifies as a healthcare entity, any:

(1) Drug indicated for a bleeding or clotting disorder, or anemia;

(2) Blood collection container approved under section 505 of the Federal Food, Drug, and Cosmetic Act; or

(3) Drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative); as long as all of the healthcare services that the establishment provides are related to its activities as a registered blood establishment or the healthcare services consist of collecting, processing, storing,

or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided that these specimens are tested together with specimens undergoing routine donor testing. Blood establishments relying on the exclusion in this paragraph (h)(3) must satisfy all other applicable requirements of the Federal Food, Drug, and Cosmetic Act and the regulations in this part promulgated thereunder.

(i) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a comprehensive hemophilia diagnostic treatment center that is receiving a grant under section 501(a)(2) of the Social Security Act and that qualifies as a healthcare entity, any drug indicated for a bleeding or clotting disorder, or anemia, or any drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative). Comprehensive hemophilia diagnostic treatment centers relying on the exclusion in this paragraph (i) must satisfy all other applicable requirements of the Social Security Act and the regulations in this part promulgated thereunder.

■ 7. In § 203.30, revise paragraphs (a)(4) and (c) to read as follows:

§ 203.30 Sample distribution by mail or common carrier.

(a) * * *

(4) The receipt is returned to the manufacturer or authorized distributor of record from which the drug sample was received.

* * * * *

(c) *Contents of the receipt to be completed upon delivery of a drug sample.* The receipt is to be on a form designated by the manufacturer or authorized distributor of record, and is required to contain the following:

(1) If the drug sample is delivered to the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner's designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(2) If the drug sample is delivered to the pharmacy of a hospital or other healthcare entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner; the name and address of the hospital or healthcare entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

■ 8. In § 203.31, revise paragraphs (a)(4), (c), (d) introductory text, (d)(2)(iii), and (e) to read as follows:

§ 203.31 Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer).

(a) * * *

(4) The receipt is returned to the manufacturer or authorized distributor of record; and

* * * * *

(c) *Contents of the receipt to be completed upon delivery of a drug sample.* The receipt is to be on a form designated by the manufacturer or authorized distributor of record, and is required to contain the following:

(1) If the drug sample is received at the address of the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner's designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(2) If the drug sample is received by the pharmacy of a hospital or other healthcare entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner; the name and address of the hospital or healthcare entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(d) *Inventory and reconciliation of drug samples of manufacturers' and authorized distributors' representatives.* Each drug manufacturer or authorized distributor of record that distributes drug samples by means of representatives shall conduct, at least annually, a complete and accurate physical inventory of all drug samples. All drug samples in the possession or control of each manufacturer's and authorized distributor's representatives are required to be inventoried and the results of the inventory are required to be recorded in an inventory record, as specified in paragraph (d)(1) of this section. In addition, manufacturers and authorized distributors of record shall reconcile the results of the physical inventory with the most recently completed prior physical inventory and create a report documenting the reconciliation process, as specified in paragraph (d)(2) of this section.

* * * * *

(2) * * *

(iii) A record of drug sample distributions since the most recently completed inventory showing the name and address of each recipient of each sample unit shipped, the date of the shipment, and the proprietary or established name, dosage strength, and number of sample units shipped. For the purposes of this paragraph (d)(2)(iii) and paragraph (d)(2)(v) of this section, ''distributions'' includes distributions to healthcare practitioners or designated hospital or healthcare entity pharmacies, transfers or exchanges with other firm representatives, returns to the manufacturer or authorized distributor of record, destruction of drug samples by a sales representative, and other types of drug sample dispositions. The specific type of distribution must be specified in the record;

* * * * *

(e) *Lists of manufacturers' and authorized distributors' representatives.* Each drug manufacturer or authorized distributor of record who distributes drug samples by means of representatives shall maintain a list of the names and addresses of its representatives who distribute drug samples and of the sites where drug samples are stored.

■ 9. In § 203.34, revise paragraph (b)(1) to read as follows:

§ 203.34 Policies and procedures; administrative systems.

* * * * *

(b) * * *

(1) Reconciling requests and receipts, identifying patterns of nonresponse, and the manufacturer's or authorized distributor of record's response when such patterns are found;

* * * * *

■ 10. In § 203.36, revise paragraph (a) to read as follows:

§ 203.36 Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party recordkeeping.

(a) *Responsibility for creating and maintaining forms, reports, and records.* Any manufacturer or authorized distributor of record that uses a fulfillment house, shipping or mailing service, or other third party, or engages in a comarketing agreement with another manufacturer or authorized distributor of record to distribute drug samples or to meet any of the

requirements of PDMA, PDA, or this part, remains responsible for creating and maintaining all requests, receipts, forms, reports, and records required under PDMA, PDA, and this part.

* * * * *

■ 11. In § 203.37, revise paragraph (e) to read as follows:

§ 203.37 Investigation and notification requirements.

* * * * *

(e) *Whom to notify at FDA.* Notifications and reports concerning samples of human prescription drugs or biological products that are regulated by the Center for Drug Evaluation and Research shall be made via email to *PDMAREPORTS@fda.hhs.gov.* Alternatively, reports and correspondence concerning such samples may be made via regular mail to the Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, ATTN: PDMA Reports. Notifications and reports concerning samples of human prescription biological products regulated by the Center for Biologics Evaluation and Research shall be made to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002.

Subpart E [Removed and Reserved]

■ 12. Remove and reserve subpart E, consisting of § 203.50.

Dated: January 24, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–01927 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. FDA–2011–N–0446]

Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment; Withdrawal

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the withdrawal of the proposed rule ''Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment,'' published in the **Federal Register** on July 14, 2011. FDA is taking this action because the proposed changes are duplicative of another FDA proposed rulemaking, which is also being published in this issue of the **Federal Register**, that is intended to conform with newly established definitions and requirements set out by the Drug Supply Chain Security Act of 2013 (DSCSA).

DATES: The proposed rule published July 14, 2011 (76 FR 41434), is withdrawn as of February 4, 2022.

ADDRESSES: For access to the docket, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Center for Drug Evaluation and Research, Office of Compliance, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–9362, *AaronWeisbuch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Quality and Security Act (DQSA) was enacted on November 27, 2013. The DQSA contains two titles: Title I, the Compounding Quality Act, and Title II, the DSCSA (Pub. L. 113–54). The DSCSA amended Chapter V of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding Subchapter H (Pharmaceutical Distribution Supply Chain), sections 581 through 585 (21 U.S.C. 360eee through 360eee–4), and by amending section 503(e) of the FD&C Act (21 U.S.C. 353(e)). As amended, sections 503(e) and 583 of the FD&C Act require the Secretary to establish national prescription drug wholesale distributor licensure standards. In addition, section 582 of the FD&C Act establishes prescription drug product tracing requirements for wholesale distributors and their trading partners.

On July 14, 2011, FDA proposed to remove § 203.50(a) (21 CFR 203.50(a)). Before that rulemaking was finalized, the DSCSA was enacted. Section 204 of the DSCSA amended section 503(e)(1) through (3) of the FD&C Act with additional and different requirements for wholesale distributors. The DSCSA also added new requirements for wholesale distributors, including phased-in prescription drug tracing requirements in section 582(c) of the FD&C Act. Because of the changes to requirements for wholesale distributors under the DSCSA, the Agency's proposed rule published on July 14, 2011, to remove § 203.50(a), was never finalized.

In its proposed rulemaking entitled ''Certain Requirements Regarding Prescription Drug Marketing,'' published elsewhere in this issue of the **Federal Register**, FDA will propose a rule that will seek to amend part 203 (21 CFR part 203) to remove provisions no longer in effect and incorporate conforming changes following enactment of the DSCSA. In the proposed rulemaking, the Agency will clarify provisions to avoid potential confusion with the new standards for wholesale distribution established by the DSCSA. The amendments to part 203 in the proposed rule will include the removal of § 203.50 in its entirety, rendering the proposed rule published July 14, 2011, removing § 203.50(a), obsolete.

II. Withdrawal of the Proposed Rule

As result of these efforts, FDA is withdrawing the proposed rule ''Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment,'' published in the **Federal Register** of July 14, 2011.

The withdrawal of this proposed rule does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposal. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment. Furthermore, this proposed rule is only intended to address the withdrawal of the proposed rule on ''Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment,'' published in the **Federal Register** of July 14, 2011, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn proposed rule, visit the Agency's website at *https://www.fda.gov* for any current information on the matter.

Dated: January 24, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–01928 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0893]

RIN 1625–AA87

Security Zone for Navy Diving Exercise; Gastineau Channel, Juneau, AK

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary security zone for certain waters of the Gastineau Channel. This action is necessary to protect personnel, vessels, and the marine environment from potential hazards created by a Navy diving excercise involving remotely operated vehicles (ROVs) and accompanying divers on these navigable waters between the Juneau-Douglas Bridge and Savikko Park near Juneau, AK from March 6, 2022, through March 17, 2022. This proposed rulemaking would prohibit persons and vessels from being in the security zone unless authorized by the Captain of the Port Southeast Alaska or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before February 14, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2021–0893 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Jesse Collins, Waterways Management Division, U.S. Coast Guard; telephone 907–463–2846, email *Jesse.O.Collins@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP Captain of the Port Southeast Alaska
CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
ROV(s) Remotely Operated Vehicle(s)
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Depatment of Navy has notified the Coast Guard that it will be conducting a diving exercise from 6 a.m. to 6 p.m., each day from March 6, 2022, through March 17, 2022, along the entire length of the Gastineau Channel. Hazards associated with the exercise include collision and damage to remotely operated vehicles (ROVs) and collision and injury to divers in the water. The Captain of the Port Southeast Alaska (COTP) has determined that potential hazards associated with the exercise would be a security concern for anyone within a 200-yard radius of the Navy vessel displaying the Alpha (''Dive'') flag.

The purpose of this rulemaking is to ensure safety of the public as well as the Navy personnel and assets in the navigable waters before, during, and after the scheduled diving exercise. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The COTP is proposing to establish a security zone from March 6, 2022, through March 17, 2022. The security zone would be enforced daily from 6 a.m. to 6 p.m. and would cover all navigable waters within 200-yard radius of the Navy vessel displaying the Alpha (''Dive'') flag in the Gastineau Channel. The duration of the zone is intended to protect Navy personnel and assets on these navigable waters before, during, and after the scheduled 6 a.m. to 6 p.m. diving exercise. No vessel or person would be permitted to enter the security zone without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed 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 NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and time of day of the security zone. Traffic is limited during the time of year when the security zone would be in effect. As a moving security zone assigned to a Navy vessel rather than a defined area of water, the impact to the waterway would be minimized. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under

the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would 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. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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 proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a security zone lasting 12 hours for twelve days that would prohibit entry within 200-yard radius of the Navy vessel displaying the Alpha (''Dive'') flag. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2021–0893 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

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 is proposing to amend 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.T17–0893 to read as follows:

§ 165.T17–0893 Security Zone for Navy Diving Exercise; Gastineau Channel, Juneau, AK.

(a) *Location.* The following area is a security zone: All the waters in Juneau Harbor and along the Gastineau Channel within a 200-yard radius of a Navy vessel displaying the Alpha (''Dive'') flag.

(b) *Definitions.* As used in this section:

(1) *Captain of the Port (COTP)* means the Commander, U.S. Coast Guard Sector Juneau.

(2) *Designated representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Southeast Alaska to assist in enforcing the security zone described in paragraph (a) of this section.

(c) *Regulations.* (1) Under the general security zone regulations in subpart D of this part, you may not enter the security zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative. All vessels underway within this security zone at the time it is activated are to depart the zone.

(2) To seek permission to enter, contact the COTP or the COTP's designated representative by telephone

at 907–463–2980 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio VHF–FM channel 16 (156.8 MHz).

(3) Those in the security zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement officials.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement period.* This section is effective from March 6, 2022, through March 17, 2022, but will only be subject to enforcement from 6 a.m. to 6 p.m. each day.

Dated: February 1, 2022.

M.S. Gillman,

Commander, U.S. Coast Guard, Acting Captain of the Port Southeast Alaska.

[FR Doc. 2022–02510 Filed 2–3–22; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 201 and 202

[Docket No. 2022–1]

Remitter Payment Options and Deposit Account Requirements

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Copyright Office is issuing a notice of proposed rulemaking regarding regulations related to remitter payments for Office services and requirements for maintaining a deposit account. Currently, payment options are addressed in various sections of Office regulations, and the method of payment accepted varies depending on the service provided. Additionally, payment methods currently referenced in the regulations may not necessarily reflect the types that the Office can accept or may choose to accept in the future. Amendments in this rulemaking are intended to consolidate regulatory provisions related to payment options and update regulations to articulate current Office practices. The Office also is proposing to simplify requirements for maintaining a deposit account and to clarify procedures related to noncompliant accounts. The Office invites public comments on this proposed rule.

DATES: Written comments must be received no later than 11:59 p.m. Eastern Time on March 7, 2022.

ADDRESSES: For reasons of governmental efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office website at *http://copyright.gov/rulemaking/remitterpaymentoptions.* If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Megan Efthimiadis, Assistant to the General Counsel, by email at *meft@copyright.gov* or telephone at (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

A. Remitter Payments

The Copyright Act provides the Copyright Office with the authority to collect fees for its services, such as registration of a copyright claim and recordation of a transfer of copyright ownership.[1] General fee-setting authority is provided in 17 U.S.C. 708(a), which enumerates ten services for which fees shall be required, along with providing authority ''to fix fees for other services.'' [2] Several sections of the Copyright Act provide the Copyright Office with explicit authority to collect fees for services not listed in section 708(a), such as designating an agent to receive notifications of claimed infringement [3] and filing a notice of intent to enforce a restored copyright.[4] A number of other fees are set pursuant to the Copyright Office's general regulatory authority, such as the fee for providing notice to libraries and archives of normal commercial exploitation or availability of a copyrighted work at a reasonable price under 17 U.S.C. 108(h)(2)(B).

The majority of regulations addressing payment methods accepted by the Copyright Office for the fees it charges appear in 37 CFR 201.6; a number of other provisions address payment methods for specific services. Some of the payment options vary depending on the service—for example, the Office accepts payment by ''electronic funds transfer, credit or debit card, or deposit account'' for online applications for registration,[5] while it accepts payment by ''money order, check, bank draft, deposit account,'' and most major credit cards for registration of foreign works restored under 17 U.S.C. 104A.[6] Some services may be paid for with cash (only in person); others may not.[7] The different payment methods across provisions can lead to confusion if not spelled out in regulations.

As part of broader modernization efforts, the Office is reviewing its regulations and updating them where necessary to reflect current and anticipated practices.[8] The Office is undertaking this rulemaking as part of those efforts, which the Office anticipates will result in an integrated, unified IT system for its services, including payment processing.

The Office issued a notification of inquiry (''NOI'') on Registration Modernization on October 17, 2018,[9] that invited public comment on a number of issues concerning regulations and practices related to the registration of copyright claims. Among the questions, the Office asked whether it should eliminate ''payment options via check or money order'' for copyright registration applications.[10] This proposed rule, in part, reflects feedback that the Office received from commenters regarding payment methods. As this notice of proposed rulemaking does not address every issue raised in that notification of inquiry or by commenters, the Office reserves judgment on any matters not expressly discussed herein; no inference should be drawn from the Office's silence on any particular point. The comments received in response to the notification of inquiry that were not addressed by this proposed rule will continue to be evaluated by the Office as system development progresses.

B. Deposit Accounts

The Copyright Office maintains a system of deposit accounts for frequent users of Office services. An individual or entity may establish a deposit account, make contributions to that account, and charge copyright fees against the balance instead of sending

[1] 17 U.S.C. 708(a).

[2] *Id.*

[3] 17 U.S.C. 512(c)(2).

[4] *Id.* 104A(e)(1)(C).

[5] 37 CFR 202.3(b)(2)(i)(C).

[6] *Id.* 202.12(c).

[7] *Compare* 37 CFR 201.6 *with id.* 201.33(e), 201.39(g), 202.12(c).

[8] A list of all recent rulemakings can be found on the Copyright Office's website at *https://www.copyright.gov/rulemaking/.*

[9] Registration Modernization, 83 FR 52336 (Oct. 17, 2018).

[10] 83 FR at 52338.

separate payments with applications and other requests for services. This process has been valued by deposit account holders, who have found it to be more efficient and less expensive than alternatives, and also to facilitate good recordkeeping and accounting practices—for example, by allowing companies to track and attribute specific payments to specific projects and business units.

Although the Copyright Act does not require the Copyright Office to offer and maintain deposit accounts,[11] the Office has done so as a convenience to high-volume users of its services since 1910.[12] Under current regulations, deposit account holders are required to engage in a minimum of 12 transactions per year and maintain a minimum balance (no less than $450) to hold a deposit account.[13] In addition, the regulations direct the Office to close a deposit account if it is overdrawn twice within any 12-month period and offer deposit account holders the option of automatic replenishment of their account via bank account or credit card.[14]

These existing administrative requirements were created through a final rule that went into effect May 1, 2011.[15] The rule arose from a proceeding that the Copyright Office began on July 14, 2009, to solve problems associated with the suspension of paper registration applications for lack of deposit account funds.[16] The Office had initially proposed to eliminate the ability to pay for paper applications using deposit accounts and to require deposit account holders to file their applications electronically.[17] After considering public comments on the proposal, the Office ''was persuaded that mandatory electronic application was not the most appropriate solution to its problem of underfunded paper applications.'' [18] The Office explored other options for addressing this problem and subsequently proposed the above account-maintenance requirements.[19] Following favorable public comments, the Office promulgated the current regulations.[20]

The Copyright Office more recently has been reviewing its deposit account regulations as part of its broader modernization efforts.[21] In May 2017, as part of those efforts, the Office sought comments on recordation modernization and solicited public comments on ''whether or not to continue allowing remitters to pay through deposit accounts . . . including whether potential users of deposit accounts would be willing to pay a surcharge for the development and maintenance of an automated deposit account system.'' [22] All respondents opposed the elimination of deposit accounts.[23]

In October 2018, the Copyright Office sought public comment on issues related to modernization of the registration system.[24] Although the October 17, 2018, NOI did not expressly mention deposit accounts, it sought comment on whether the Office should eliminate ''payment options via check or money order.'' [25] In answering that question, several respondents reiterated support for deposit accounts.[26]

Through its review, the Office has identified several areas where the current regulations could be improved. As a threshold matter, the Office recognizes that many stakeholders benefit from the ability to maintain deposit accounts, and the Office continues to support their availability.[27] The intent of this proceeding is to ensure that the Office is able to continue to provide deposit accounts in an efficient and cost-effective manner that aligns with user expectations, the overall operations of the Office, and the broader goals of the copyright system.

First, although the regulations prescribe minimum transaction and balance requirements, they do not prescribe any procedure for addressing noncompliant deposit accounts. The Copyright Office has periodically reviewed existing deposit accounts for noncompliance and has an internal procedure for closing noncompliant deposit accounts. The process is designed to provide clear notice to noncompliant deposit account holders and an opportunity to cure within a reasonable time period. Communicating a process through regulations would increase transparency, clarity, and certainty.

Second, the establishment and maintenance of deposit accounts create costs to the Copyright Office above other payment methods. These costs include staff time to establish, maintain, and reconcile accounts and invest excess balances, as well as developing and sustaining internal controls necessary to manage unused deposit account balances (which the Office must hold as a fiduciary for deposit account holders until they use the funds or the Office refunds them).

The Copyright Office previously proposed establishing fees in connection with the creation and maintenance of deposit accounts,[28] though it ultimately decided against doing so. In 1994, the Office, after noting that ''the Copyright Office deposit account system involves substantial benefits to the depositors and substantial costs to the Copyright Office,'' proposed a fee of $50 to open a deposit account and an annual maintenance fee of $50 (the average cost of providing the service at the time).[29] Along with the fees, the Office proposed eliminating the minimum 12

[11] The Copyright Act does, however, authorize the Office to ''request the Secretary of the Treasury to invest in interest-bearing securities in the United States Treasury any portion of the fees that, as determined by the Register, is not required to meet current Deposit Account demands.'' 17 U.S.C. 708(d)(2).

[12] U.S. Copyright Office, *Rules and Regulations for the Registration of Claims to Copyright* at 16 (1910).

[13] 37 CFR 201.6(b).

[14] *Id.*

[15] Administration of Copyright Office Deposit Accounts, 76 FR 9229 (Feb. 17, 2011).

[16] 76 FR at 9229.

[17] *Id.* at 9230 (citing 74 FR 33930 (July 14, 2009)).

[18] *Id.*

[19] *Id.* (citing 75 FR 62345 (Oct. 8, 2010)).

[20] *Id.*

[21] For more information on the Office's modernization efforts generally, see *https://www.copyright.gov/copyright-modernization/.*

[22] Modernizing Copyright Recordation, 82 FR 22771 (May 18, 2017).

[23] *See* Ent. Software Ass'n Modernizing Copyright Recordation Comments at 6–7; Software and Info. Ass'n of Am. Modernizing Copyright Recordation Comments at 2; Motion Picture Ass'n of Am. Modernizing Copyright Recordation Comments at 2–3; Author Services Modernizing Copyright Recordation Comments at 2; Copyright All. Modernizing Copyright Recordation Comments at 2; Am. Ass'n of Indep. Music, Recording Indus. Ass'n of Am., & Nat'l Music Publishers' Ass'n Modernizing Copyright Recordation Comments at 3–4; Intell. Prop. Owners Ass'n Modernizing Copyright Recordation Comments at 2. Comments are available at *https://copyright.gov/rulemaking/recordation-modernization/.*

[24] Registration Modernization, 83 FR 52336 (Oct. 17, 2018).

[25] 83 FR at 52338.

[26] *See* Am. Intell. Prop. Law Ass'n Registration Modernization 2018 NOI Comments at 2; Copyright All. Registration Modernization 2018 NOI Comments at 8; Int'l Trademark Ass'n Registration Modernization 2018 NOI Comments at 3–4; Motion Picture Ass'n of Am. Registration Modernization 2018 NOI Comments at 4; Nat'l Music Publishers' Ass'n Registration Modernization 2018 NOI Comments at 6–7; Shaftel & Schmeltzer Registration Modernization 2018 NOI Comments at 4. Comments are available at *https://copyright.gov/rulemaking/reg-modernization/.*

[27] *See* Administration of Copyright Office Deposit Accounts, 76 FR 9229, 9231 (Feb. 17, 2011) (''[T]he Copyright Office acknowledged in its October 8, 2010 notice that Deposit Accounts remain a useful and efficient option for copyright owners who frequently use its services, including, but not limited to, registration, and announced that it will continue to offer Deposit Accounts for the foreseeable future, reserving its prerogative to revisit the question of their utility and cost to the Office at a later time.'').

[28] Fees, 59 FR 38369, 38371 (July 28, 1994).

[29] 59 FR at 38400.

transactions per year requirement.[30] The Office subsequently abandoned implementing any fees following public comment.[31] The Office maintained that position again in 1998, as part of a general fee rulemaking, explaining that ''the use of deposit accounts is beneficial both to the holder and the Office.'' [32]

Third, the current deposit account regulations allow for automatic replenishment of funds and state that a deposit account that was closed due to a second overdraft within a 12-month period ''can be re-opened only if the holder elects to fund it through automatic replenishment.'' [33] But the Copyright Office does not have the practical ability to accept automatic replenishment, either as a convenience for replenishment or as a means for re-opening a closed account, via the most-commonly used payment methods. *Pay.gov*—a U.S. Treasury Department system for secure processing of payments to federal government agencies that the Office uses to administer payment for electronic services—currently only allows automatic payments via ACH; it does not permit automatic payments to be made by other payment methods, such as credit cards. Accordingly, the regulations need to be revised to reflect current Office capabilities.

II. Proposed Rule

Having carefully considered the above issues, including relevant public comments in prior proceedings, the Copyright Office now issues a proposed rule amending its regulations regarding remitter payments and deposit accounts and invites further public comment on any aspects of the amended rules.

A. Remitter Payments

The Copyright Office proposes amending its regulations governing remitter payments as follows. First, the Office proposes to consolidate all regulations related to the types of payment methods it will accept for services into a single set of provisions. This will ensure accuracy and consistency in payment methods across the Office's services, particularly as the Office moves to an integrated enterprise IT system.[34] The rule enumerates the payment methods accepted for three different avenues: Electronic payments, mailed payments, and payments provided in person at the Office's Public Information Office. Electronic payments must be made through *Pay.gov,* which accepts most common types of electronic payment methods. For mailed payments, the Office will only accept checks or money orders. The Office will accept checks, money orders, credit card, debit card, and currency for services requested in person, along with electronic payments made via *Pay.gov* if done by appointment at the Public Information Office kiosk.

Although cash transactions are the costliest transactions to process, the Copyright Office notes that, prior to the pandemic-related suspension of in-person services,[35] the Public Information Office received a not insignificant volume of cash payments,[36] and that eliminating the acceptance of cash might limit access to Office services for some individuals. The Office will continue to explore ways to ensure the widest accessibility of its services while exercising fiscal responsibility, including the possibility of adding a surcharge to cash payments to offset their processing costs and incentivizing payment through less expensive methods.[37]

B. Deposit Accounts

The Copyright Office proposes simplifying requirements to maintain a deposit account and identifying in regulations the deposit account closure procedures. First, the Office proposes that a deposit account holder no longer be required to engage in a minimum number of transactions per year. The Office proposes to eliminate this requirement for several reasons. For one, as noted above, the rationale that led to the creation of the minimum-transactions requirement—that without a minimum-transaction requirement deposit account holders would neglect account balances and leave ''insufficient funds to process a paper application'' [38]—has lessened. The percentage of service requests the Office receives by paper, as opposed to electronically, has declined significantly since the requirement was created and is expected to continue to drop; [39] a lower proportion of paper applications reduces the likelihood of deposit account holders overdrawing because the Office's electronic system will not process a request if a deposit account lacks sufficient funds. Additionally, the imposition of a service charge for a deposit account that falls below the minimum balance, as discussed below, will create additional incentives for deposit account holders to maintain sufficient funds for service requests. Finally, the costs associated with monitoring transaction numbers outweigh any benefit the minimum-transaction requirement provides in reducing overdrafts. For deposit account holders, the elimination of the minimum-transaction requirement should ease their own regulatory burdens.

Second, the Copyright Office proposes imposing a service charge of $25 for each month a deposit account balance is below $450.[40] As pointed out above, this will incentivize deposit account holders to maintain sufficient funds in deposit accounts to avoid overdrafts. The Office notes that the U.S. Patent and Trademark Office currently imposes a similar service charge in connection with its deposit accounts.[41] The Copyright Office will not assess the service charge until the last day of the first full calendar month in which the account balance remains below the minimum balance in order to provide deposit account holders with sufficient opportunity to replenish the account before incurring the charge, and an account with less than $25 at the end of a month will be inactivated by the Office rather than incur the service charge.

Third, the proposed rules provide for the inactivation of accounts in two circumstances. One is when an account has had no activity for 24 months. Though the Office proposes to eliminate the minimum-transactions requirement, providing for inactivation when an account goes unused for such a prolonged period will reduce the costs

[30] *Id.* at 38401.

[31] Fees, 63 FR 15802, 15803 (Apr. 1, 1998) (noting that, based on the comments received in response to the fees proposed in 1994, see 59 FR at 38400, ''the Office decided not to move forward with any charges'' for maintaining deposit accounts).

[32] 63 FR at 15803.

[33] 37 CFR 201.6(b)(2).

[34] Library of Congress & U.S. Copyright Office, *Modified U.S. Copyright Office Provisional IT Modernization Plan* at 7 (Sept. 1, 2017), *http://www.copyright.gov/reports/itplan/modified modernization-plan.pdf.*

[35] *See* Operations Updates During the COVID–19 Pandemic, U.S. Copyright Office, *https://www.copyright.gov/coronavirus/.*

[36] These amounts were $9,154.66 in 2018 and $6,498.30 in 2019.

[37] The Office already has a model for this: Fees for registration applications submitted via paper are higher than the fees for electronic applications. *See* 37 CFR 201.3.

[38] 76 FR at 9229.

[39] In the fourth quarter of FY2011, paper registration applications amounted to about 16% of all applications. *See Annual Report of the Register of Copyrights, Fiscal Year Ending September 30, 2011,* at 22. Currently, they amount to less than 1% of all applications. *See* Registration Processing Times, U.S. Copyright Office, *https://www.copyright.gov/registration/docs/processing-times-faqs.pdf* (last visited Jan. 4, 2022).

[40] Deposit Account balances will be reviewed and recorded at the end of the final day of each month.

[41] *See* 37 CFR 2.6(b)(11); *see also* Deposit Account Rules and Information, U.S. Patent and Trademark Office, *https://www.uspto.gov/learning-and-resources/fees-and-payment/deposit-account-rules-and-information* (last visited Jan. 4, 2022).

associated with maintaining unused accounts. The other circumstance is after several unsuccessful attempts to contact the deposit account holder. Undeliverable accounts create burdens for the Copyright Office, and these procedures will alleviate them.

Fourth, the rules spell out the Copyright Office's procedures for closing noncompliant deposit accounts, including the circumstances for closure and the process for returning any remaining funds to the deposit account holder. Currently, the Office's closure procedures are not explicitly set out in regulations. Adding them will provide additional transparency, clarity, and certainty regarding Office deposit account policies.

Finally, the Copyright Office is eliminating references to automatic replenishment of deposit accounts. At this time, *Pay.gov* lacks the ability to provide such automatic replenishment.

List of Subjects

37 CFR Part 201

Copyright, General provisions.

37 CFR Part 202

Preregistration and registration of claims to copyright.

For reasons stated in the preamble, the Copyright Office proposes to amend 37 CFR parts 201 and 202 as follows:

PART 201—GENERAL PROVISIONS

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

■ 2. Amend § 201.3 by redesignating paragraphs (d)(2) through (17) as paragraphs (d)(3) through (18), respectively, and adding new paragraph (d)(2).

The addition reads as follows:

§ 201.3 Fees for registration, recordation, and related services, special services, and services performed by the Licensing Division.

* * * * *

(d) * * *

Registration, recordation and related services	Fees ($)
* * * * * * *	
(2) Service charge for each month when the deposit account balance at the end of the month is below $450	25
* * * * * * *	

■ 3. Amend § 201.6 by revising paragraphs (a) and (b) to read as follows:

§ 201.6 Payment and refund of Copyright Office fees.

(a) *In general.* (1) *Electronic payments.* All fees for online applications and services must be paid by electronic payment through *Pay.gov.*

(2) *Mailed payments.* All fees mailed to the Copyright Office should be in the form of a money order or check payable to the U.S. Copyright Office. Currency will not be accepted; any payment received in currency will be refunded via check, and the registration or other service request will not be processed. Where the statutory fee is submitted in the form of a check, the registration of the copyright claim or other record made by the Office is provisional until payment in money is received. In the event the fee is not paid, the registration or other record shall be expunged.

(3) *In-person payments.* All fees for services rendered in person at the Copyright Office Public Information Office must be paid by cash, money order, check, or credit or debit card.

(4) *Foreign remittances.* Foreign remittances must be redeemable without service or exchange fees through a United States institution, must be payable in United States dollars, and must be imprinted with American Banking Association routing numbers. Postal money orders that are negotiable only at a post office are not acceptable. International checks and money orders must be drawn from a United States bank and payable in United States dollars for the full amount of the fee required. Uncertified checks are accepted subject to collection.

(5) *Other.* In addition to the payment options in paragraphs (a)(1) through (3) of this section, payment for any application or service can be made using a Copyright Office deposit account.

(b) *Deposit accounts.* (1) *Establishment.* Persons or firms may prepay copyright expenses by establishing a deposit account.

(2) *Service charge.* The service charge prescribed at § 201.3(d)(2) is assessed at the end of the first full calendar month after a deposit account balance falls below the minimum balance requirement.

(3) *Contact information.* (i) Deposit account holders are responsible for keeping contact information with the Copyright Office current.

(ii) If the Copyright Office is unable to correspond with the deposit account holder (*e.g.,* due to returned/undeliverable postal or email), the Office will deem the deposit account undeliverable.

(iii) Undeliverable deposit accounts will continue to be charged the fee prescribed at § 201.3(d)(2) at the end of each month if the account balance remains below $450 throughout that period.

(4) *Inactivation.* (i) The Copyright Office will inactivate a deposit account if there has been no activity in the account for 24 months.

(ii) The Copyright Office will inactivate a deposit account if the deposit account holder overdraws his or her account.

(iii) The Copyright Office will inactivate a deposit account that has insufficient funds at the end of the month to pay the service charge for maintaining a deposit account with an account balance below $450.

(5) *Closure.* (i) An inactive deposit account will be closed no sooner than 30 days from the date of inactivation if insufficient funds to pay the service charge remain in the deposit account or if the service charge for maintaining a deposit account with an account balance below $450 at the end of the month has not been paid.

(ii) The Copyright Office may permanently close a deposit account if the deposit account holder overdraws his or her account twice in any calendar year.

(iii) An undeliverable deposit account will be closed after the Copyright Office has made at least three unsuccessful attempts, including at least one attempt by phone if a deposit account holder provided a telephone number, to correspond with the deposit account holder. Attempts at corresponding with the deposit account holder may be considered unsuccessful if the postal or email correspondence is returned as undeliverable.

(iv) Any funds remaining in a closed deposit account will be applied to any pending or processed service request(s) for which payment is due. If there are

insufficient funds to cover the total of all fees due for any service, the service request(s) will not be processed.

(v) Any balance remaining in a closed deposit account will be refunded to the account holder in accordance with Copyright Office policies. Unredeemed refunds will be handled in accordance with Library of Congress and U.S. Treasury rules and policies.

(vi) The Copyright Office may refer any overdraft in a closed deposit account for collections.

(6) *Further information.* For information on deposit accounts, see Circular 5 on the Copyright Office's website, or request a copy at the address specified in § 201.1(b).

* * * * *

■ 5. Amend § 201.33 by revising paragraph (e) to read as follows:

§ 201.33 Procedures for filing Notices of Intent to Enforce a restored copyright under the Uruguay Round Agreements Act.

* * * * *

(e) Fee. The filing fee for recording Notices of Intent to Enforce is prescribed in § 201.3(c).

* * * * *

§ 201.39 [Amended]

■ 6. Remove § 201.39(g)(3).

PART 202—PREREGISTRATION AND REGISTRATION OF CLAIMS TO COPYRIGHT

■ 7. The authority citation for part 202 continues to read as follows:

Authority: 17 U.S.C. 408(f), 702.

§ 202.3 [Amended]

■ 8. Amend § 202.3 by removing (b)(2)(i)(C) and redesignating paragraph (b)(2)(i)(D) as (b)(2)(i)(C).

■ 9. Amend § 202.12 by revising paragraph (c)(2) to read as follows:

§ 202.12 Restored copyrights.

* * * * *

(c) * * *

(2) Fee. The filing fee for registering a copyright claim in a restored work is prescribed in § 201.3(c) of this chapter.

* * * * *

■ 10. Amend § 202.16 by revising paragraph (c)(5) to read as follows:

§ 202.16 Preregistration of copyrights.

* * * * *

(c) * * *

(5) *Fee.* The filing fee for preregistration is prescribed in § 201.3(c).

* * * * *

■ 11. Amend § 202.23 by revising paragraph (e)(2) to read as follows:

§ 202.23 Full term retention of copyright deposits.

* * * * *

(e) * * *

(2) Payment in the amount prescribed in § 201.3(d) of this chapter payable to the U.S. Copyright Office, must be received in the Copyright Office within 60 calendar days from the date of mailing of the Copyright Office's notification to the requestor that full-term retention has been granted for a particular copyright deposit.

* * * * *

Dated: January 24, 2022.

Kimberley Isbell,

Acting General Counsel and Associate Register of Copyrights.

[FR Doc. 2022–01776 Filed 2–3–22; 8:45 am]

BILLING CODE 1410–30–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AR01

VA Pilot Program on Graduate Medical Education and Residency

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs proposes to revise its medical regulations to establish a new pilot program on graduate medical education and residency, as required by section 403 of the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Network Act of 2018.

DATES: Comments must be received on or before April 5, 2022.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to, Paul B. Greenberg, Deputy Chief, Office of Academic Affiliations, (14AA), Department of Veterans Affairs, 810 Vermont Ave. NW, Washington, DC 20420. Comments should indicate that they are submitted in response to ''RIN 2900–AR01—VA Pilot Program on Graduate Medical Education and Residency.'' Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Paul B. Greenberg, Deputy Chief, Office of Academic Affiliations, (14AA), Department of Veterans Affairs, 810 Vermont Ave. NW, Washington, DC 20420, (202) 461–9490. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: Section 403 of the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Network Act of 2018 (Pub. L. 115–182, hereafter referred to as the MISSION Act) mandated the Department of Veterans Affairs (VA) create a pilot program to establish additional medical residency positions authorized under section 7302 of title 38 United States Code (U.S.C.) (note to 38 U.S.C. 7302) at certain covered facilities. This proposed rule would establish substantive and procedural requirements to allow VA to administer this pilot program in a manner consistent with section 403 of the MISSION Act.

Section 7302(e)(1) of title 38 United States Code (U.S.C.) permits VA to both establish medical residency programs in VA facilities and ensure that such established programs have a sufficient number of residents. Section 403 of the MISSION Act created a note to section 7302 to expand VA's authority to establish medical residency positions in covered facilities to include non-VA facilities such as health care facilities of the Department of Defense and Indian Health Service. Section 403 of the MISSION Act further provides parameters for VA to determine those covered facilities in which residents will be placed. For instance, section 403 requires VA to consider certain factors to determine whether there is a clinical need for providers in areas where residents would be placed. Section 403 also requires prioritized placement of residents under the pilot program in Indian Health Service facilities, Indian tribal or tribal organization facilities, certain underserved VA facilities, or other covered facilities. Section 403 additionally authorizes VA to pay resident stipends and benefits regardless of whether such residents are assigned to a VA facility, and requires VA to pay certain startup costs of new residency programs (such as curriculum development and faculty salaries) if residents are placed in such programs under the pilot program. The authority for the pilot was initially scheduled to expire on August 7, 2024; however, it was subsequently extended to August 7, 2031, under section 5107 of Public Law 116–169.

Before detailing the regulations we propose to implement this mandated pilot program, we provide a brief summary of VA's administration of its Graduate Medical Education (GME) programming under 38 U.S.C. 7302(e), to establish a basic understanding of VA's understand of the conduct of GME programming in general. Under section 7302(e)(1), VA establishes new medical residency programs in VA facilities and

ensures that such programs have a sufficient number of residents; VA also ensures that existing medical residency programs have a sufficient number of residents. Criteria under sections 7302(e)(1)(A)–(B) and (e)(2)(A)–(B) further guide VA's selection of its facilities in which residency programs will be established or residents will be placed, where such criteria relate to VA staffing levels, location of VA facilities in certain areas deemed as health professional shortage areas, and priority for residents to be placed for the provision of specific types of health care. Through a request for proposal (RFP) mechanism, VA Central Office notifies VA facilities of these selection criteria as well as other parameters. This RFP details, among other things: Consideration factors to be assessed by VA Central Office (as well as the relative importance or weight of such factors); information required from VA facilities to be in any response to the RFP submitted back to VA Central Office; and the process to submit a response to the RFP, to include submission instructions and timelines for completion. Upon receipt of those RFP responses submitted by VA health care facilities, VA Central Office evaluates the responses submitted against the criteria in the RFP to determine those facilities in which residents will be placed or whether funding will be made available for certain costs of establishing new medical residency programs. In administering GME programming under section 7302(e), VA forms relationships with non-VA institutions that sponsor graduate medical educational programs (most often medical schools or teaching hospitals), and it is those sponsoring institutions that provide the residents that would be available for placement in VA facilities. VA, therefore, does not control the pool of participating educational programs or available residents, although VA does assess the requirements under section 7302(e) to determine the best placement for such residents in VA facilities. VA in effect then does not place residents but does provide for resident positions to be filled in VA facilities. Under section 7302(d), VA forms academic affiliations with sponsoring institutions to delineate the responsibilities regarding the training of the residents, and VA enters into other separate agreements to control funding of both certain residency program educational costs (such as accreditation fees and National Resident Match Program fees) and the costs of paying resident stipends and benefits. VA envisions that the pilot program authorized under section 403 would be conducted under the same basic tenets of GME programming as presented above, such that there would be agreements formed with academic affiliations with sponsoring institutions and the covered facilities recognized in section 403 and in which residents would be placed under the pilot. We will note throughout these proposed regulations where we expect there to be administrative and substantive similarities and differences between VA's statutory GME programming under 38 U.S.C. 7302 and the pilot program required by section 403.

We propose to establish several new regulation sections in part 17 of title 38 Code of Federal regulation (CFR) in §§ 17.243 through 17.248 to implement this mandated pilot program, as further discussed below.

§ 17.243 Purpose and scope.

Proposed § 17.243(a) would establish that proposed §§ 17.243 through 17.248 would implement the VA Pilot Program on Graduate Medical Education and Residency (PPGMER) to place residents in existing or new residency programs in covered facilities and to reimburse certain costs associated with establishing new residency programs in covered facilities, as authorized by section 403 of Public Law 115–182. Proposed § 17.243(b) would establish the scope of the PPGMER by stating that §§ 17.243 through 17.248 would apply only to the PPGMER as authorized under section 403 of Public Law 115–182, and not to VA's more general administration of GME programs in VA facilities as authorized under 38 U.S.C. 7302(e). Establishing the scope of the PPGMER as separate from VA's more general GME programming under 38 U.S.C. 7302(e) would be necessary because the PPGMER is a time-limited pilot program that will sunset on August 7, 2031 (unless statutorily reauthorized or made permanent), and because section 403 of the MISSION Act establishes PPGMER-specific criteria that do not otherwise apply to VA's administration of GME programs under 38 U.S.C. 7302(e). Additionally, although the PPGMER would be a separately administered program under these proposed regulations, the PPGMER would utilize some of the same administrative concepts or procedures as VA uses to administer programs under 38 U.S.C. 7302(e). For instance, some definitions as proposed in these regulations may be the same as established in certain VA policy used to administer GME programming under section 7302(e), as will be explained in discussion of proposed § 17.244. Proposed § 17.243 would not state the 2031 sunset date of the PPGMER, as the authority for PPGMER may be extended or made permanent in the future. If the authority for PPGMER were not extended or made permanent, VA would cease to implement the PPGMER and would issue a publication in the **Federal Register** to remove and reserve the regulation.

§ 17.244 Definitions.

Proposed § 17.244 would establish definitions to apply to the PPGMER under proposed §§ 17.243 through 17.249.

The term benefit would be defined to mean a benefit provided by VA to a resident that has monetary value in addition to a resident's stipend, which may include but not be limited to health insurance, life insurance, worker's compensation, disability insurance, Federal Insurance Contributions Act (FICA) taxes, and retirement contributions. We believe this would be a commonly understood definition of this term as it is consistent with the characterization of benefits in VA policy that is used to administer programs under the authority of 38 U.S.C. 7302(e). This definition would be relevant as VA would pay benefits to residents as applicable, as explained later in the discussion of proposed § 17.248.

The term covered facility would be defined to mean any facility identified in § 17.245, as that section is proposed and discussed later in this rulemaking. We would define covered facility in relation to proposed § 17.245, to avoid having to reference § 17.245 in every instance in which the term covered facility would be used in the proposed regulation text.

The term educational activities would be defined to mean all activities in which residents participate to meet educational goals or curriculum requirements of a residency program, to include but not be limited to: Clinical duties; attendance in didactic sessions; research; attendance at VA facility committee meetings; scholarly activities that are part of an accredited training program; and approved educational details. We believe this would be a commonly understood definition of this term as it is consistent with the characterization of existing educational activities in VA policy (see, *e.g.,* Veterans Health Administration (VHA) Directive 1400.09, Education of Physicians and Dentists) that is used to administer programs under the authority of 38 U.S.C. 7302(e). This term would be relevant as it would be used to qualify those stipend and benefits payments VA may make for residents

under the PPGMER, as explained later in the discussion of proposed § 17.248.

The term resident would be defined to mean physician trainees engaged in post-graduate specialty or subspecialty residency programs that are either accredited by the Accreditation Council for Graduate Medical Education or in the application process for accreditation. The term resident would further be defined to include individuals in their first post-graduate year (PGY–1) of training (often referred to as Interns), and individuals who have completed training in their primary specialty and continue training in a subspecialty graduate medical education program and (generally referred to as Fellows). These Fellows would often be PGY–4 and above, depending upon the specialty. This term is relevant as it would be used throughout these proposed regulations, and we believe this proposed definition would be commonly understood as it is consistent with the characterization of a resident in VA policy that is used to administer programs under the authority of 38 U.S.C. 7302(e). Because this definition would require the residency programs to be accredited or in the process for such accreditation by the Accreditation Council of Graduate Medical Education, VA would not consider individuals in non-accreditable programs, including VA Advanced Fellows or post-training chief residents, as residents under this pilot. While section 7302(e) uses the term residency position, for purposes of this proposed rule, we propose to use the term resident because that was the term used in sections 403(a)(4) through (6) and (b) of the MISSION Act. Additionally, the proposed definition of resident would permit VA to consider more than one resident as occupying a single resident position (such as a split assignment, which VA would track according to the percentage of VA assigned educational activities).

The term stipend would be defined to mean the annual salary paid by VA for a resident. We believe this proposed definition would be commonly understood as it is consistent with the characterization of a stipend in VA policy that is used to administer programs under the authority of 38 U.S.C. 7302(e). This definition would be relevant as VA would pay stipends to residents as applicable, as explained later in the discussion of proposed § 17.248.

The term VA health care facility would be defined to mean any VA-owned or VA-operated location where VA physicians provide care to Veterans, to include but not be limited to a VA medical center, independent outpatient clinic, domiciliary, nursing home (community living center), residential treatment program, and community-based clinic. This definition would be relevant to characterize one type of covered facility under proposed § 17.245, and relevant to characterize one assessment criterion under proposed § 17.246(a)(7). We believe this definition is reasonable because it would capture the VA settings in which a VA physician provides care to Veterans, as it would be physicians who are teaching residents to be placed under the PPGMER.

§ 17.245 Covered facilities.

Proposed § 17.245 would list the covered facilities in which residents may be placed under the PPGMER, consistent with section 403(a)(2) of the MISSION Act. We would restate the list of covered facilities from section 403(a)(2), versus merely cross-referencing section 403 or the statutory note to 38 U.S.C. 7302, for clarity and to provide regulatory citations that characterize or define certain terms related to covered facilities as applicable. Listing the facility types versus cross referencing section 403 would also allow proposed § 17.245 to include applicable regulatory citations. For instance, section 403(a)(2)(B) establishes that one type of covered facility are those health care facilities operated by an Indian tribe or tribal organization as those terms are defined in 25 U.S.C. 5304; proposed § 17.245(b) would restate this language from section 403 and would add the relevant regulatory citations for the definitions of Indian tribe and tribal organization.

Proposed § 17.245 would establish the following types of facilities as covered facilities under the PPGMER, consistent with section 403(a)(2) of the MISSION Act: (1) A VA health care facility as defined in § 17.244; (2) a health care facility operated by an Indian tribe or tribal organization, as those terms are defined in 25 U.S.C. 5304 and at 25 CFR 273.106; (3) a health care facility operated by the Indian Health Service; (4) a federally-qualified health center as defined in 42 U.S.C. 1396d(l)(2)(B); (5) a health care facility operated by the Department of Defense; or (6) other health care facilities deemed appropriate by VA. We note that although a VA health care facility is listed as a covered facility under section 403(a)(2)(A) and would also be listed as a covered facility in proposed § 17.245(a), we do not anticipate the PPGMER being a vehicle for the placement of residents in VA facilities, as VA intends to continue operating its GME programming to place residents in VA facilities as authorized under 38 U.S.C. 7302 and 7406, separate from the PPGMER for the duration in which the PPGMER is implemented. We believe the authority under section 7302 is sufficient to place residents in VA facilities. However, we would not want to exclude from this proposed rule an express type of covered facility as listed in section 403(a)(2) of the MISSION Act. Similarly, proposed § 17.245(f) would provide, consistent with section 403(a)(2)(F), that a covered facility could be any other health care facility as VA considers appropriate, giving VA the ability to place residents in a variety of facilities, such as those recognized by the Department of Health and Human Services as Rural Health Clinics, without curtailing the discretion provided to VA by section 403(a)(2)(F) in the administration of the PPGMER.

§ 17.246 Consideration factors for placement of residents.

Proposed § 17.246 would establish factors that VA would consider when determining in which covered facilities residents would be placed under the pilot. Consistent with section 403(a)(4)(A)–(G) of the MISSION Act, proposed § 17.246(a)(1) through (7) would generally provide that VA would evaluate these factors in the context of whether there is a clinical need for providers in the area in which a covered facility is located. Proposed paragraphs (a)(1) through (7) would then restate from section 403(a)(4)(A)–(G) the specific factors VA must consider when determining whether there is a clinical need for providers in an area (those specific factors are discussed in detail further in this section of the preamble). We note that these proposed factors, consistent with section 403(a)(4), would not be weighted in any particular manner in the regulation text under proposed § 17.246(a), to allow flexibility for VA to consider the relative import of factors throughout the duration of the pilot. Although these factors would not be weighted in regulatory text, it may be the case that VA would assign levels of relative importance to these factors as part of its selection process, as discussed in the section of this preamble related to proposed § 17.247. Additionally, only one factor in proposed paragraphs (a)(1) through (7) would be required to be met for VA to determine that a covered facility would be in an area with a clinical need for providers. As discussed below, it may be the case that some covered facilities could be considered to meet the same factor under paragraphs (a)(1) through (7) of proposed § 17.246, and that

additional factors would need to be considered.

Before discussing the specific factors that VA would consider in proposed § 17.246(a)(1) through (7) to determine the clinical need for providers in an area, we clarify that VA would not be soliciting the interest of covered facilities to participate in the PPGMER through a public funding announcement, a public request for proposal, or by establishing an public application process, because section 403 of the MISSION Act is not an express grant or cooperative agreement authority through which VA may offer a public funding opportunity. Further, section 403 does not authorize any amount of money to be appropriated to implement the PPGMER, separate from VA's administration of its existing GME programing authorized under 38 U.S.C. 7302 and 7406. Because VA does not interpret that section 403 of the MISSION Act to authorize a public funding opportunity for which covered facilities may apply or submit a proposal to be considered, VA would not conduct a public solicitation. Rather, the parameters of VA's selection process for covered facilities would be established in proposed § 17.247, as discussed later in this proposed rule.

Consistent with section 403(a)(4)(A) of the MISSION Act, proposed § 17.246(a)(1) would establish that VA would evaluate the ratio of veterans to VA providers for a standardized geographic area surrounding a covered facility, including a separate ratio for general practitioners and specialists. Proposed § 17.246(a)(1)(i) would establish that VA considers a standardized geographic area to mean the county in which a covered facility is located. We believe this is a reasonable interpretation of a standardized geographic area by which to compare ratios of veterans to VA providers, as most covered facilities as well as VA should be able to access such data. We understand that proposing to use a county as the standardized geographic area would mean that covered facilities in the same county would have the same ratios of veterans to VA providers, making such facilities incomparable in terms of this consideration factor. We reiterate, therefore, that this is only one of multiple factors that VA would consider when determining the need for clinical providers in an area, and we do not anticipate that this factor would prevent covered facilities in the same county from being considered, provided other factors that indicate clinical need are met. Proposed § 17.246(a)(1)(ii) would clarify that when deciding the clinical need for providers in an area, VA may consider either or both of the ratio(s) for general practitioners and specialists, where a higher ratio of veterans to VA providers would indicate a higher need for health care providers in an area. We believe these clarifications would be consistent with section 403(a)(4)(A).

Consistent with section 403(a)(4)(B) of the MISSION Act, proposed § 17.246(a)(2) would establish that VA would evaluate the range of clinical specialties of VA and non-VA providers for a standardized geographic area surrounding a covered facility, where the presence of fewer clinical specialties indicates a higher need for health care providers in an area, which we believe is a reasonable interpretation of section 403(a)(4)(B) to reflect a commonplace understanding that fewer types of providers in an area can indicate a greater clinical need. Proposed § 17.246(a)(2) would consider the range of specialties of both VA and non-VA providers in an area because section 403(a)(4)(B) is not specific to only VA providers. We note that the term standardized geographic area as used in proposed § 17.246(a)(2) would mean the county in which a covered facility is located, consistent with how that term is defined in proposed § 17.246(a)(1)(i).

Consistent with section 403(a)(4)(C) of the MISSION Act, proposed § 17.246(a)(3) would establish that VA would evaluate whether the specialty of a provider is included in the most recent staffing shortage determination by VA under 38 U.S.C. 7412. Under section 7412(a), not later than September 30 of each year, the Inspector General of VA shall determine, certain clinical and nonclinical occupations for which there are the largest staffing shortages with respect to each VA medical center of the Department. The type of providers considered under proposed § 17.246(a)(3) would be based on the list developed pursuant to 38 U.S.C. 7412(a). We note that the list developed pursuant to 38 U.S.C. 7412(a) is a national list (based on data from all VA medical centers in the country related to shortages of providers), and that this factor would not be evaluated in relation to provider types or numbers at any one VA facility. We also note that a covered facility would not similarly have to have a shortage of the type of provider on the list developed pursuant to 38 U.S.C. 7412, as it may be that a sufficient number of such providers at a covered facility could indicate the best conditions in which VA should place residents (as these would be the very types of providers VA needs more of). We would not regulate this factor more specifically, however, to provide VA the flexibility in assessing the list developed pursuant to 38 U.S.C. 7412.

Consistent with section 403(a)(4)(D) of the MISSION Act, proposed § 17.246(a)(4) would establish that VA would evaluate whether a covered facility is located in the local community of a VA facility that has been designated by VA as an underserved facility pursuant to criteria developed under section 401 of Public Law 115–182. We note that section 403(a)(4)(D) of the MISSION Act would require VA to consider whether the local community is designated as underserved pursuant to criteria developed under section 401 of Public Law 115–182. Section 401 of Public Law 115–182 relates to VA's criteria to designate its facilities as underserved, rather than communities at large. To clarify any potential inconsistency between the reference to underserved VA facilities in section 401 and underserved communities in section 403, we believe a reasonable reading of section 403(a)(4)(D) provides for VA to consider whether covered facilities are located in a local community in which a VA facility has been designated as underserved under section 401. In developing the criteria to identify underserved VA facilities under section 401, VA must consider various factors, including the ratio of veterans to VA health care providers in an area, the range of clinical specialties offered, whether the local community is medically underserved, data on open consults, whether the facility is meeting the wait-time goals of the Department, and such other factors that VA considers important in determining which facilities are not adequately serving area veterans. For purposes of this factor, if a covered facility is located in the same Veterans Integrated Service Network (VISN) as a VA facility designated as underserved pursuant to section 401, then VA would consider that covered facility to be located in the same local community as the VA facility. We believe the service area of a VISN would allow VA to consider a broad range of covered facilities, but we would not regulate that requirement more specifically in the event that VA facility service area names change in the future. Using the phrase local community in proposed § 17.246(a)(4) would also be consistent with section 403(a)(4)(D) of the MISSION Act, and would allow VA the flexibility to consider a service area that is different from a VISN in the future, in which case VA would clearly indicate a different standard in the request for proposal that is sent to VA health care facilities for consideration.

Lastly, we note that under section 401, a VA facility is characterized as a medical center, ambulatory care facility, and a community-based outpatient clinic. Proposed § 17.246(a)(4) would reference VA facility to be consistent with section 401.

Consistent with section 403(a)(4)(E) of the MISSION Act, proposed § 17.246(a)(5) would establish that VA would evaluate whether the covered facility is located in a community designated by the Secretary of Health and Human Services (HHS) as a health professional shortage area under 42 U.S.C. 254e. Under 42 U.S.C. 254e(a)(1), a health professional shortage is an area in an urban or rural area that has been determined to have a provider shortage and which is not reasonably accessible to an adequately served area, a population group that has been determined to have such a shortage, or a public or nonprofit private medical facility or other public facility that has been determined to have such a shortage.

Consistent with section 403(a)(4)(F) of the MISSION Act, proposed § 17.246(a)(6) would establish that VA would evaluate whether the covered facility is in a rural or remote area. Proposed paragraph (a)(6)(i) would further interpret a rural area to mean those areas identified by the U.S. Census Bureau as rural. Section 403 does not specifically define or characterize the meaning of the term rural, and therefore, we believe it is rational to use the definition provided by the U.S. Census Bureau. The Census Bureau's classification of rural consists of all territory, population, and housing units located outside of urbanized areas and urban clusters. Interested parties are referred to the Census Bureau's website (*https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html*) for additional information. Proposed paragraph (a)(6)(ii) would further interpret a remote area to mean an area within a zip-code designated as a frontier and remote area (FAR) code by the Economic Research Service within the United States Department of Agriculture, based on the most recent decennial census and to include all identified FAR code levels. VA would adopt this characterization of a remote area because it does not have a similarly comprehensive characterization of remote areas in statute or regulation. As we are unsure of the level of familiarity with this standard related to a frontier or remote area, as opposed to the characterization of a rural area as proposed above, we provide the following background. The Economic Research Service within the United States Department of Agriculture has developed ZIP-code-level FAR designations, where the phrase frontier and remote is used to describe territory characterized by some combination of low population size and high geographic remoteness. The most updated set of FAR codes is based on urban-rural data from the 2010 decennial census and provides four FAR definition levels, ranging from one that is relatively inclusive (12.2 million FAR level one residents) to one that is more restrictive (2.3 million FAR level four residents). FAR areas are defined in relation to the time it takes to travel by car to the edges of nearby urban areas, and four FAR levels are necessary because rural areas experience degrees of remoteness at higher or lower population levels that affect access to different types of goods and services. For instance, a larger number of people live significant distances from cities providing high order goods and services, such as advanced medical procedures, stores selling major household appliances, regional airport hubs, or professional sports franchises, and level one FAR codes are meant to approximate this degree of remoteness. A smaller number of people have difficulty accessing low order goods and services, such as grocery stores, gas stations, and basic health-care services, and level-four FAR codes more closely coincide with this higher degree of remoteness. Other types of goods and services—clothing stores, car dealerships, movie theaters—fall somewhere in between. We would use all four levels of FAR codes to characterize remote areas for purposes of these proposed rules.

Consistent with 403(a)(4)(G) of the MISSION Act, proposed § 17.246(a)(7) would implement VA's permissive authority, for purposes of resident placements under PPGMER, to evaluate other criteria that VA considers important in determining those covered facilities that are not adequately serving area veterans. Proposed paragraph (a)(7) would include a non-exhaustive list of criteria VA would consider. Proposed § 17.246(a)(7)(i) would establish that VA may evaluate the proximity of a non-VA covered facility to a VA health care facility, such that residents placed in non-VA covered facilities may also receive training in VA health care facilities. This criterion would be useful in assessing to what extent residents placed in non-VA covered facilities could reasonably be expected to travel to also receive resident training in VA health care facilities, consistent with the requirement that the discretionary criteria in section 403(a)(4)(G) of the MISSION Act relate to identifying those covered facilities that may not be adequately serving area veterans. For purposes of assessing the criterion in proposed § 17.246(a)(7)(i), VA would define a VA health care facility to mean any VA location where VA physicians provide care to Veterans, such as a VA medical center, independent outpatient clinic, domiciliary, nursing home (community living center), residential treatment program, and any of a variety of community-based clinics. We note that this definition is broader than the term ''VA facility'' under proposed § 17.246(a)(4), as proposed § 17.246 would relate to an independent characterization of the term VA facility under section 401 of Public Law 115–182. We also note that proposed § 17.246(a)(7)(i) does not create any requirement for residents placed under the PPGMER to necessarily rotate to VA facilities to receive training, it is merely one additional criterion that VA may assess in accordance with section 403(a)(4)(G) of the MISSION Act. Any requirement for rotation to VA facilities for residents placed under the PPGMER, like other training requirements for such residents, would be controlled by the agreements formed as will be discussed in the section of this rule that addresses proposed § 17.248. Proposed § 17.246(a)(7)(ii) would establish that VA may evaluate programmatic considerations related to establishing or maintaining a sustainable residency program when determining facilities are not adequately serving area veterans, for purposes of placing residents in covered facilities. These programmatic considerations would include but not be limited to whether the stated objectives of a residency program align with VA's workforce needs; the likely or known available educational infrastructure of a new residency program or existing residency program (including the ability to attract and retain qualified teaching faculty); and the ability of the residency program to remain financially sustainable after the cessation of any financial support from VA that may be furnished under proposed § 17.248. These considerations would allow VA to assess the likelihood of a residency program to be successful and sustainable, thus ensuring VA's resources in funding residents would be well placed to support the PPGMER.

Proposed § 17.246(b) would establish that there would be a prioritized placement of residents under the PPGMER to no fewer than 100 residents for the duration in which the PPGMER

is administered in covered facilities operated by either the Indian Health Service, an Indian tribe, a tribal organization, or covered facilities located in the same areas as VA facilities designated by VA as underserved pursuant to criteria developed under section 401 of Public Law 115–182. This minimum number of residents to be placed in these specific covered facilities is consistent with the requirement in section 403(a)(5) of the MISSION Act. Proposed § 17.246(b) would further clarify that the placement of these 100 residents would be for the duration in which the PPGMER is administered, because we do not read anything in section 403(a)(5) to require these 100 residents to be the first residents placed under this pilot program. We also interpret section 403(a)(5) of the MISSION Act to require VA to consider priority placement of at least 100 residents and not 100 resident positions, which is consistent with a plain reading of section 403(a)(5). We clarify this point because we would define the term resident to permit multiple residents to occupy a single resident position as appropriate. We note that, generally, residents placed through the PPGMER could be at any point in their residency, and that any such placement at any point in a residency would qualify amongst the 100 priority placements in proposed § 17.246.

§ 17.247 Determination process for placement of residents.

We reiterate from earlier in this proposed rule that VA does not interpret that section 403 authorizes a public funding opportunity through which covered facilities or any other entity may apply or submit a proposal to VA, for VA to then consider having residents placed in covered facilities and paying their stipends or benefits, or to reimburse certain costs of new residency programs. The introductory text to proposed § 17.247 would therefore state that section 403 of Public Law 115–182 does not authorize a grant program or cooperative agreement program through which covered facilities or any other entity may apply for residents to be placed in covered facilities or to apply for VA to pay or reimburse costs under § 17.248 (where proposed § 17.248, as discussed later in this rulemaking, would establish VA's payment of resident stipends and benefits, and VA's reimbursement of certain costs of new residency programs). The introductory text to proposed § 17.247 would further establish that VA will therefore not conduct a public solicitation to determine those covered facilities in which residents may be places or to determine costs that may be paid or reimbursed under § 17.248, but that VA would instead make such determinations based on the parameters further established in proposed § 17.247(a) through (c).

Proposed § 17.247(a) would state that VA Central Office will issue a request for proposal (RFP) to VA health care facilities to announce opportunities for residents to be placed in covered facilities and to have costs paid or reimbursed under § 17.248 (as explained later in this rulemaking, proposed § 17.248 will outline the types of costs available to be paid or reimbursed by VA under the PPGMER.) Proposed § 17.247(a) would further state that the RFP issued by VA Central Office would describe, at a minimum: (1) Consideration factors, to include the criteria in § 17.246, that will be used to evaluate any responses to the RFP, as well as the relative importance of such consideration factors; (2) information required to be in any responses to the RFP; and (3) the process to submit a response to the RFP. Under proposed § 17.247(a), the RFP issued by VA Central Office would provide education to VA health care facilities in the evaluation of the factors in proposed § 17.246(a)(1) through (7) to determine clinical need for providers in an area, and the VA health care facilities would then assess covered facilities that may be located in such areas to weigh the factors and determine those covered facilities that meet the criteria under the RFP. We reiterate from earlier in this rulemaking that VA Central Office conducts an RFP process to administer its more general GME programming under section 7302(e), and VA envisions a similar process to be followed under the PPGMER, where VA Central Office notifies VA facilities (directly, or through channels via Veterans Integrated Service Networks) of a forthcoming RFP cycle for the funding of residents or certain resident program costs. The RFP in turn would provide VA health care facilities with all required information to complete a response, including a clear statement of the consideration factors and submission instructions to include any submission dates as applicable and points of contact for questions. The RFP will additionally provide a general timeline in which VA health care facilities will conduct the process of assessing the consideration factors and reaching out to covered facilities regarding the RFP. The consideration factors in the RFP for the PPGMER would include those consideration factors expressly stated in section 403(a)(4) and in proposed § 17.246, and the relative importance of such factors (*e.g.,* whether they may be weighted differently). We reiterate from earlier in the preamble that the consideration factors in proposed § 17.246 would not be weighted in the regulatory text itself to allow VA the flexibility to consider the relative importance of factors over the duration of the pilot, as the relative importance of those factors may change. For instance, an RFP issued by VA Central Office for the PPGMER could indicate that there would be more weight assigned to areas that issued responses with covered facilities operated by Indian Health Service, an Indian tribe, a tribal organization, or covered facilities located in the same areas as VA facilities designated by VA as underserved, as these are deemed priority placement factors for the PPGMER in section 403(a)(5). Alternatively, an RFP issued by VA Central Office for the PPGMER could indicate that there would be more weight assigned depending on the specialty of a provider included in the most recent staffing shortage determination by VA under 38 U.S.C. 7412.

Proposed § 17.247(b) would then establish that VA health care facilities, in collaboration with covered facilities, will submit responses to the RFP to VA Central Office. This language would permit only VA health care facilities to submit responses to the RFP issued by VA Central Office, to further reinforce VA's interpretation that section 403 does not authorize a public funding opportunity for which covered facilities may apply directly or submit a proposal to be considered. VA health care facilities would assess covered facilities in their areas that participate with institutions that sponsor medical educational programs (most often a medical school or teaching hospital), where typically VA already has academic partnerships with such sponsoring institutions and the RFP details the involvement of any particular sponsoring institution. However, VA would not be prevented in these proposed regulations from assessing covered facilities that did not have educational relationships with sponsoring institutions, and covered facilities would not be prevented from initiating contact with a VA facility to determine if such covered facilities may meet the requirements to participate in the PPGMER as detailed in the RFP. We reiterate that the RFP will provide a general timeline in which VA health

care facilities will conduct the process of assessing the consideration factors and reaching out to covered facilities regarding the RFP.

Proposed § 17.247(c) would then state that VA Central Office will evaluate responses to the RFP from VA health care facilities and will determine those covered facilities where residents may be placed and costs under § 17.248 are paid or reimbursed. In its evaluation, VA Central Office will assess the consideration factors established in the RFP to include the criteria in § 17.246, and will weigh those factors as their relative importance would be established in the RFP.

§ 17.248 Costs of funding residents and new residency programs.

Proposed § 17.248 would establish the types of costs that VA may fund under the PPGMER to place residents in covered facilities or to reimburse certain costs incurred by new residency programs in accordance with sections 403(a)(6) and (b)(1)–(b)(5) of the MISSION Act. Section 403(a)(6) authorizes VA to pay stipends and provide benefits for residents in positions created under section 403(a)(1), and section 403(b) authorizes VA to reimburse certain new residency program costs if VA places a resident in such a program.

To address a few preliminary matters, we note that section 403(a)(6) is a discretionary authority to pay stipends and benefits of residents, regardless of whether they have been assigned to a VA facility, and that VA would retain this discretion in proposed § 17.248 to include establishing any general restrictions or conditions for such payments. We further interpret the discretionary nature of section 403(a)(6) to authorize VA's funding of resident stipends and benefits either through a direct payment or reimbursement mechanism, in accordance with any contract, agreement, or other arrangement VA has legal authority to form (possibly, to include payment mechanisms as applicable that VA currently uses to administer its more general GME programming under 38 U.S.C. 7302(e)). Conversely, we interpret section 403(b) as a mandatory authority to reimburse certain new resident program costs if VA places a resident in such programs, and further that subsections (b)(1)–(b)(5) establish the mandatory costs that must be reimbursed. However, we do not interpret that section 403(b) limits VA's authority to determine restrictions or criteria for such reimbursement. Lastly, consistent with section 403(a)(3), and other authorities under which VA may legally enter into contracts, agreements, or other arrangements, VA would enter into such contracts, agreements, or other arrangements to administer the PPGMER. It would be those contracts, agreements, or other arrangements that would establish the terms to control costs that could be funded.

The introductory text of proposed § 17.248 would establish that once VA determines in which covered facilities residents will be placed, in accordance with §§ 17.246 through 17.247, payment or reimbursement of certain costs would be authorized. Proposed § 17.248(a) would establish the first category of funding available under the PPGMER, related to resident stipends and benefits, consistent with section 403(a)(6). Proposed § 17.248(a) would establish that, for residents placed in covered facilities by VA, VA may pay only the proportionate cost of resident stipends and benefits that are associated with residents participating in educational activities directly related to the PPGMER. This language is intended to limit payments of stipend and benefits to only those educational activities that support the PPGMER, to prevent VA's payment for educational activities a resident may complete when they may engage in duties or responsibilities associated with portions of their training not associated with the PPGMER (such as when a resident may have portions of their training paid for by other entities not engaged with the PPGMER). We clarify that educational activities directly related to the PPGMER could be associated with the treatment of non-veteran patients, as section 403(a)(6) of the MISSION Act clearly permits VA to pay stipends and benefits for residents outside of VA facilities, and section 403(b) permits VA to reimburse certain costs associated with new residency programs established in covered facilities, which includes non-VA facilities. More generally, a primary purpose of VA's administration of GME programming under 38 U.S.C. 7302(e), and under section 403 of the MISSION Act by extension, is to fulfill one of VA's missions under 38 U.S.C. 7302 to assist in providing an adequate supply of health personnel to the United States. We reiterate from the discussion of proposed § 17.246(a)(7)(i) that this rule would not create any requirement for residents placed under the PPGMER to necessarily rotate to VA health care facilities to receive training, and any such requirement (as with other training requirements for PPGMER residents) would be controlled by the agreements formed as discussed further in this section of the rule related to proposed § 17.248. Proposed § 17.248(a) would further state that VA's payment of stipends and benefits would be in accordance with any contract, agreement, or other arrangement VA has legal authority to form. In addition, such stipends and benefits will not exceed VA's established maximum amounts for payments under any existing GME agreements. This language intends to establish that any criteria or restrictions related to VA's payment of stipends and benefits would be clearly indicated in contracts, agreements, or other arrangements outside of the proposed rule. This language would allow VA the flexibility to establish payment parameters as would be relevant to a covered facility, within the appropriate purchasing or other mechanisms that VA may legally use, to include an agreement permitted under section 403(a)(3) of Public Law 115–182. We note that VA would be bound by any legal requirements as they exist outside of this proposed rule with regards to these other authorities to enter into contracts, agreements, or other arrangements. Proposed § 17.248(a) would not state or reference these other authorities, or the resulting payment instruments, however, to provide VA and covered facilities the flexibility that would be needed to properly implement the payment of resident stipends and benefits.

Proposed § 17.248(b) would establish that VA may reimburse certain costs associated with new residency programs, consistent with section 403(b)(1)–(5) of the MISSION Act. Consistent with section 403(b), proposed § 17.248(b)(1) would establish that if a covered facility establishes a new residency program in which VA places a resident, VA will reimburse certain costs as further detailed in proposed § 17.248(b)(1)(i) through (v), where the following costs in proposed paragraphs (b)(1)(i) through (v) mirror the types of costs established in sections 403(b)(1)–(5), which are: Curriculum development costs; recruitment and retention of faculty costs; accreditation costs; faculty salary costs; and resident education expense costs. Each of the types of costs established in proposed § 17.248(b)(1)(i) through (v) would be further characterized by the following non-exhaustive examples: (1) Curriculum development costs would include but not be limited to costs associated with needs analysis, didactic activities, materials, equipment, consultant fees, and instructional design; (2) recruitment and retention of faculty costs would include but not be

limited to costs associated with advertising available faculty positions, and monetary incentives to fill such positions such as relocation costs and educational loan repayment; (3) accreditation costs would include but not be limited to the administrative fees incurred by a covered facility in association with applying for only initial accreditation of the program by the Accreditation Council for Graduate Medical Education; (4) faculty salary costs would include only the proportionate cost of faculty performing duties directly related to the PPGMER; and (5) resident education expense costs, to include but not be limited to costs associated with the required purchase of medical equipment and required training, national resident match program participation fees, and residency program management software fees. We further note that faculty salary costs in proposed § 17.248(b)(1)(iv) would have a similar qualifying restriction as with resident stipends and benefits in proposed § 17.248(a), where faculty salary costs would be limited to only the proportionate cost of faculty performing duties directly related to the PPGMER. This restriction would provide an express notice that VA would not, for instance, reimburse costs for any portion of salary of an attending physician that correlates with supervising residents that were not participating in the PPGMER, as it may be the case that a group of residents being supervised by an attending physician is not fully comprised of PPGMER participants. Similar to proposed § 17.248(a), proposed § 17.248(b) would further state that VA's reimbursement of certain costs associated with a new residency program would be in accordance with any contract, agreement, or other arrangement VA has legal authority to form, and that reimbursements for authorized costs may not exceed VA's established maximum amounts for payment under any existing GME agreements. This language intends to establish that any criteria or restrictions related to VA's reimbursement of these costs would be clearly indicated in contracts, agreements, or other arrangements outside of the proposed rule, again to allow the flexibility to establish parameters as would be relevant and within the appropriate purchasing or reimbursement mechanisms that VA may legally use. We note that VA would be bound by any legal requirements as exist outside of this proposed rule with regards to these other authorities to enter into contracts, agreements, or other arrangements, but that proposed § 17.248(b) would not state or reference these other authorities, again to provide VA and covered facilities the flexibility that would be needed to properly implement the reimbursement of these costs.

Although proposed § 17.248(a) and (b) would not state any express criteria or restrictions that might exist in contracts, agreements, or other arrangements that would control the payment of resident stipends or benefits or reimbursement of certain new residency program costs, some examples of such criteria or restrictions could include: Establishing a discontinuation date for payments or reimbursements; establishing limitations on payments proportionate to the number of residents placed by VA; establishing any fixed dollar amount limits as found relevant or appropriate; or establishing a restricted look-back period, whereby VA would not reimburse the costs of, for instance, certain curriculum development costs that might occur prior to a specified timeframe before VA places a resident. Similarly, proposed § 17.248(a) and (b) would not expressly list the legal authorities or types of contracts, agreements, or other arrangements under which VA may pay resident stipends or benefits, or reimburse certain costs of new residency programs, or more generally to administer other typical aspects of GME programming through the PPGMER. Again, this lack of specificity with regards to identifying specific legal instruments in regulation would allow VA maximum flexibility to administer the PPGMER. However, we reiterate from earlier in this rulemaking that VA would otherwise be bound by any legal requirements as exist outside of this proposed rule with regards to these other authorities to enter into contracts, agreements, or other arrangements. We also reiterate from earlier in this rulemaking that VA would seek to administer the PPGMER in much the same manner as VA's more general GME programming is administered under 38 U.S.C. 7302(e), as would be applicable and permissible, which would likely include the forming of certain agreements between VA and sponsoring institutions to establish responsibilities for educating residents and to control VA's funding of residents and certain costs of new residency programs, or the evidence that such agreements were formed between sponsoring institutions and non-VA covered facilities. We therefore provide the following examples of types of agreements VA uses to administer its more general GME programming under section 7302(e), to provide some idea of whether the same or similar instruments might also be used to administer the PPGMER. Under VA's more general GME programming pursuant to 38 U.S.C. 7302(e), VA uses an affiliation agreement to delineate the duties and responsibilities regarding the training of residents, where an affiliation agreement is a central part of the relationship between VA and the affiliated institution and may involve specific provisions related to patient care, education, or research. Affiliated institutions can include academic institutions and other sponsoring institutions such as community hospitals, clinics, state agencies military treatment facilities, or Federal Health Education Consortia. VA would look to an affiliation agreement or similar instrument to form similar relationships with entities to administer the PPGMER. We note that VA policy currently recognizes sponsoring institutions and other entities as able to enter into an affiliation agreement prior to a subject residency program receiving comprehensive or full accreditation, such as an institution whose residency program may have some stage of Accreditation Council for Graduate Medical Education (ACGME) initial or provisional accreditation. See VHA Handbook 1400.03, Veterans Health Administration Educational Relationships. Under the PPGMER, we would retain VA's ability to enter into affiliation agreements or similar instruments or look to the formation of such instruments between sponsoring institutions and non-VA covered facilities, where the subject residency programs may have some form of initial or provisional ACGME accreditation.

Under VA's more general GME programming pursuant to 38 U.S.C. 7302(e), a disbursement agreement is used to administer stipend and benefits payments to residents in VA facilities. A disbursement agreement is an agreement through which VA allows a disbursing agent to administer salary payments and fringe benefits for medical residents assigned to a VA facility, where the disbursing agent may be the sponsoring institution for the residency training program itself or an entity delegated by the sponsoring institution(s) to handle stipend and benefit disbursements (*e.g.,* a graduate medical education consortium). VA may look to a similar instrument to administer stipend and benefits payments for residents it places in non-VA facilities under the PPGMER, or any other contract, agreement, or

other arrangement VA may enter into as permissible and applicable.

Under VA's more general GME programming pursuant to 38 U.S.C. 7302(e), VA uses educational cost contracts to pay pro-rated educational costs of the affiliated institutions sponsoring residency programs. These educational cost contracts are entered into pursuant to 38 U.S.C. 8153, where the relevant health care resource being purchased includes health care support resources and administrative resources to include the operation of a residency program. The pro-rated educational costs to be covered are set forth in an educational cost contract in proportion to the number of residents that actually rotate to a VA facility. VA may look to a similar instrument to administer payments of costs associated with the PPGMER, or any other contract, agreement, or other arrangement VA may enter into as permissible and applicable.

VA also generally uses memoranda of agreement or understanding (MOA or MOU) as legally permissible to enter into agreements with entities and may look to such instruments to administer payments of costs associated with the PPGMER or to administer other aspects of the PPGMER. For instance, a MOA or MOU might be used to clearly indicate to a covered facility the extent of reimbursable costs allowable under proposed § 17.248(b), and could also include instructions for submitting to VA invoices of such costs and timeframes and modes of reimbursement.

Proposed § 17.248(b)(2) would lastly establish that VA considers new residency programs as only those residency programs that have initial ACGME accreditation or have continued ACGME accreditation without outcomes, and have not graduated an inaugural class, at the time VA has determined those covered facilities where residents will be placed under § 17.247(c). We believe the ACGME status of initial accreditation or continued ACGME accreditation without outcomes captures those residency programs still in development and that would benefit from VA's reimbursement of certain start-up costs in establishing a residency program. The additional criterion that such programs must not have graduated an inaugural class further supports that VA funding will not go to residency programs that otherwise have fully functioning curriculums and infrastructure to produce graduates. The ACGME status of initial accreditation is considered a developmental stage where residency programs can accept residents, and this status allows for site visits to determine compliance with relevant ACGME standards. As background, when a status of initial accreditation is conferred on a sponsoring institution or program, that institution or program will have a full site visit within two years of the effective date of initial accreditation, where the effective date is the date of the decision by the ACGME review committee (or, any effective date such committee may apply retroactively to the beginning of the academic year). If a residency program does not matriculate residents in the first academic year after receiving a status of initial accreditation, a site visit is conducted within three years from the effective date of such accreditation. If a sponsoring institution or program demonstrates substantial compliance at the subsequent review, the ACGME review committee may confer a status of continued accreditation or continued accreditation without outcomes. Proposed § 17.248(b)(2) would only include the ACGME status of continued accreditation without outcomes, beyond the initial accreditation stage, because continued accreditation without outcomes indicates that no residents have graduated, which in turn may indicate that the residency program still requires VA funding of certain costs to fully develop its curriculum and infrastructure.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

Regulatory Flexibility Act

The Secretary hereby certifies that this rulemaking would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The residents to be placed for training in covered facilities and to have certain stipend and benefits costs paid for by VA are individuals and not small entities. To the extent that any covered facilities are small entities, there is no significant economic impact because the rulemaking would only permit VA's reimbursement and not payment of certain costs associated with certain start up costs associated with new residency programs, there is no funding opportunity for which covered facilities may apply to be considered and otherwise no economic gain or loss for covered facilities associated with this rule. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Except for emergency approvals under 44 U.S.C. 3507(j), VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. This proposed rule contains no provisions constituting a collection of information under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3521).

Assistance Listing

The Assistance Listing program numbers and titles for the programs affected by this document are 64.011—Veterans Dental Care; 64.026—Veterans State Adult Day Health Care; 64.040—VHA Inpatient Medicine; 64.041—VHA Outpatient Specialty Care; 64.042—VHA Inpatient Surgery; 64.043—VHA Mental Health Residential; 64.045—VHA Outpatient Ancillary Services; 64.046—VHA Inpatient Psychiatry; 64.047—VHA Primary Care; 64.048—VHA Mental Health clinics; 64.050—VHA Diagnostic Care; 64.054—Research and Development.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on October 8, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. Amend the authority citation for part 17 by adding an entry for §§ 17.243 through 17.248 in numerical order to read in part as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

Sections 17.243 through 17.248 are also issued under 38 U.S.C. 7302 note.

* * * * *

■ 2. Add an undesignated center heading and §§ 17.243 through 17.248 to read as follows:

VA Pilot Program on Graduate Medical Education and Residency

Sec.

17.243 Purpose and scope.
17.244 Definitions.
17.245 Covered facilities.
17.246 Consideration factors *for placement of residents.*
17.247 Determination process for placement of residents.
17.248 Costs of placing residents and new residency programs.

VA Pilot Program on Graduate Medical Education and Residency

§ 17.243 Purpose and scope.

(a) *Purpose.* This section and §§ 17.244 through 17.248 implement the VA Pilot Program on Graduate Medical Education and Residency (PPGMER), which permits placement of residents in existing or new residency programs in covered facilities and permits VA to reimburse certain costs associated with establishing new residency programs in covered facilities, as authorized by section 403 of Public Law 115–182.

(b) *Scope.* This section and §§ 17.244 through 17.248 apply only to the PPGMER as authorized under section 403 of Public Law 115–182, and not to VA's more general administration of graduate medical residency programs in VA facilities as authorized under 38 U.S.C. 7302(e).

§ 17.244 Definitions.

For purposes of §§ 17.243 through 17.248:

Benefit means a benefit provided by VA to a resident that has monetary value in addition to a resident's stipend, which may include but not be limited to health insurance, life insurance, worker's compensation, disability insurance, Federal Insurance Contributions Act taxes, and retirement contributions.

Covered facility means any facility identified in § 17.245.

Educational activities mean all activities in which residents participate to meet educational goals or curriculum requirements of a residency program, to include but not be limited to: Clinical duties; research; attendance in didactic sessions; attendance at facility committee meetings; scholarly activities that are part of an accredited training program; and approved educational details.

Resident means physician trainees engaged in post-graduate specialty or subspecialty training programs that are either accredited by the Accreditation Council for Graduate Medical Education or in the application process for such accreditation. A resident may include an individual in their first post-graduate year (PGY–1) of training (often referred to as an intern), and an individual who has completed training in their primary specialty and continues training in a subspecialty graduate medical education program (generally referred to a fellow).

Stipend means the annual salary paid by VA for a resident.

VA health care facility means any VA-owned or VA-operated location where VA physicians provide care to Veterans, to include but not be limited to a VA medical center, independent outpatient clinic, domiciliary, nursing home (community living center), residential treatment program, and community-based clinic.

§ 17.245 Covered facilities.

A covered facility is any of the following:

(a) A VA health care facility;

(b) A health care facility operated by an Indian tribe or tribal organization, as those terms are defined in 25 U.S.C. 5304 and at 25 CFR 273.106;

(c) A health care facility operated by the Indian Health Service;

(d) A federally-qualified health center as defined in 42 U.S.C. 1396d(l)(2)(B);

(e) A health care facility operated by the Department of Defense; or

(f) Other health care facilities deemed appropriate by VA.

§ 17.246 Consideration factors for placement of residents.

(a) *General.* When determining in which covered facilities residents will be placed, VA shall consider the clinical need for health care providers in an area, as determined by VA's evaluation of the following factors:

(1) The ratio of veterans to VA providers for a standardized geographic area surrounding a covered facility, including a separate ratio for general practitioners and specialists.

(i) For purposes of paragraphs (a)(1) and (2) of this section, standardized geographic area means the county in which the covered facility is located.

(ii) VA may consider either or both of the ratio(s) for general practitioners and specialists, where a higher ratio of veterans to VA providers indicates a higher need for health care providers in an area.

(2) The range of clinical specialties of VA and non-VA providers for a standardized geographic area surrounding a covered facility, where the presence of fewer clinical specialties indicates a higher need for health care providers in an area.

(3) Whether the specialty of a provider is included in the most recent staffing shortage determination by VA under 38 U.S.C. 7412.

(4) Whether the covered facility is in the local community of a VA facility that has been designated by VA as an underserved facility pursuant to criteria developed under section 401 of Public Law 115–182.

(5) Whether the covered facility is located in a community that is designated by the Secretary of Health and Human Services as a health professional shortage area under 42 U.S.C. 254e.

(6) Whether the covered facility is in a rural or remote area, where:

(i) A rural area means an area identified by the U.S. Census Bureau as rural; and

(ii) A remote area means an area within a zip-code designated as a frontier and remote area (FAR) code by the Economic Research Service within the United States Department of Agriculture, based on the most recent decennial census and to include all identified FAR code levels.

(7) Such other criteria as VA considers important in determining those covered facilities that are not adequately serving area veterans. These factors may include but are not limited to:

(i) Proximity of a non-VA covered facility to a VA health care facility, such that residents placed in non-VA covered facilities may also receive training in VA health care facilities.

(ii) Programmatic considerations related to establishing or maintaining a sustainable residency program, such as: Whether the stated objectives of a residency program align with VA's workforce needs; the likely or known available educational infrastructure of a new residency program or existing residency program (including the ability to attract and retain qualified teaching faculty); and the ability of the residency program to remain financially sustainable after the cessation of funding that VA may furnish under § 17.248.

(b) *Priority in placements.* For the duration in which the PPGMER is administered, no fewer than 100 residents will be placed in covered facilities operated by either the Indian Health Service, an Indian tribe, a tribal organization, or covered facilities located in the same areas as VA facilities designated by VA as underserved pursuant to criteria developed under section 401 of Public Law 115–182.

§ 17.247 Determination process for placement of residents.

Section 403 of Public Law 115–182 does not authorize a grant program or cooperative agreement program through which covered facilities or any other entity may apply for residents to be placed in covered facilities or to apply for VA to pay or reimburse costs under § 17.248. VA therefore will not conduct a public solicitation to determine those covered facilities in which residents may be placed or to determine costs that may be paid or reimbursed under § 17.248. VA will instead determine those covered facilities in which residents may be placed and determine any costs to be paid or reimbursed under § 17.248 in accordance with the following parameters:

(a) VA Central Office will issue a request for proposal (RFP) to VA health care facilities to announce opportunities for residents to be placed in covered facilities and to have costs paid or reimbursed under § 17.248. This RFP will describe, at a minimum:

(1) Consideration factors to include the criteria in § 17.246, that will be used to evaluate any responses to the RFP, as well as the relative importance of such consideration factors;

(2) Information required to be in any responses to the RFP; and

(3) The process to submit a response to the RFP.

(b) VA health care facilities, in collaboration with covered facilities, will submit responses to the RFP to VA Central Office.

(c) Consistent with paragraph (a) of this section, VA Central Office will evaluate responses to the RFP from VA health care facilities and will determine those covered facilities where residents may be placed and costs under § 17.248 are paid or reimbursed.

§ 17.248 Costs of placing residents and new residency programs.

Once VA determines in which covered facilities residents will be placed in accordance with §§ 17.246 through 17.247, payment or reimbursement is authorized for the following costs:

(a) *Resident stipends and benefits.* For residents placed in covered facilities, VA may pay only the proportionate cost of resident stipends and benefits that are associated with residents participating in educational activities directly related to the PPGMER, in accordance with any contract, agreement, or other arrangement VA has legal authority to form.

(b) *Costs associated with new residency programs.* (1) If a covered facility establishes a new residency program in which a resident is placed, VA will reimburse the following costs in accordance with any contract, agreement, or other arrangement VA has legal authority to form.

(i) Curriculum development costs, to include but not be limited to costs associated with needs analysis, didactic activities, materials, equipment, consultant fees, and instructional design.

(ii) Recruitment and retention of faculty costs, to include but not be limited to costs associated with advertising available faculty positions, and monetary incentives to fill such positions such as relocation costs and educational loan repayment.

(iii) Accreditation costs, to include but not be limited to the administrative fees incurred by a covered facility in association with applying for only initial accreditation of the program by the Accreditation Council for Graduate Medical Education (ACGME).

(iv) Faculty salary costs, to include only the proportionate cost of faculty performing duties directly related to the PPGMER.

(v) Resident education expense costs, to include but not be limited to costs associated with the required purchase of medical equipment and required training, national resident match program participation fees, and residency program management software fees.

(2) VA considers new residency programs as only those residency programs that have initial ACGME accreditation or have continued ACGME accreditation without outcomes, and have not graduated an inaugural class, at the time VA has determined those covered facilities where residents will be placed under § 17.247(c).

[FR Doc. 2022–02292 Filed 2–3–22; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2018–0746; FRL–6494.1–01–OAR]

RIN 2060–AV54

Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reconsideration of final rule.

SUMMARY: On August 12, 2020, the U.S. Environmental Protection Agency (EPA) published the final National Emission Standards for Hazardous Air Pollutants (NESHAP): Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review. Subsequently, the Agency received and granted petitions for reconsideration on two issues, specifically, the use of the EPA's 2016 Integrated Risk Information System (IRIS) value for ethylene oxide in assessing cancer risk for the source category and the use of the Texas Commission on Environmental Quality (TCEQ) risk value for ethylene oxide as an alternative risk value to the EPA's IRIS value. Here, the EPA is addressing these two issues and is also requesting public comment. The EPA is seeking comment only on the two identified petition issues. The EPA will not respond to comments addressing any other issues or any other provisions of the final rule.

DATES:

Comments. Comments must be received on or before March 24, 2022.

Public hearing: If anyone contacts us requesting a public hearing on or before February 9, 2022, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2018–0746, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2018–0746 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2018–0746.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2018–0746, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are open to the public by appointment only to reduce the risk of transmitting COVID–19. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Ms. Tegan Lavoie, Sector Policies and Programs Division (E–143–01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5110; and email address: *lavoie.tegan@epa.gov.*

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. Please note that because of the current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, the EPA cannot hold in-person public meetings at this time.

If requested, the virtual hearing will be held on February 22, 2022. The hearing will convene at 11:00 a.m. Eastern Time (ET) and will conclude at 7:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission.*

The EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission* or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* The last day to pre-register to speak at the hearing will be February 16, 2022. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing, if requested, however, please plan for the hearings to run either ahead of schedule or behind schedule.

If a hearing is requested, each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *lavoie.tegan@epa.gov.* The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing, if requested, will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission.* While the EPA expects the hearing, if requested, to go forward as set forth above, please monitor our website to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by February 11, 2022. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2018–0746. All documents in the docket are listed in *https://www.regulations.gov/.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. With the exception of such material, publicly available docket materials are available electronically in *Regulations.gov.*

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2018–

0746. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Due to public health concerns related to COVID–19, the Docket Center and Reading Room are open to the public by appointment only. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2018–0746. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

Preamble acronyms and abbreviations. Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ACC American Chemistry Council
AIC Akaike Information Criterion
ATSDR Agency for Toxic Substances and Disease Registry
CAA Clean Air Act
CBI Confidential Business Information
CFR Code of Federal Regulations
DSD Development Support Document
EPA Environmental Protection Agency
HAP hazardous air pollutant(s)
IRIS Integrated Risk Information System
MACT maximum achievable control technology
MON Miscellaneous Organic Chemical Manufacturing NESHAP
NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NIOSH National Institute for Occupational Safety and Health
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OAR Office of Air and Radiation
OMB Office of Management and Budget
PRA Paperwork Reduction Act
RFA Regulatory Flexibility Act
RFC request for correction
RTR residual risk and technology review
SAB Science Advisory Board
SSM startup, shutdown, and malfunction
TCEQ Texas Commission on Environmental Quality
UMRA Unfunded Mandates Reform Act
URE unit risk estimate

Organization of this document. The information in this preamble is organized as follows:

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I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51
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I. General Information

A. What is the statutory authority for the reconsideration action?

The statutory authority for this action is provided by sections 112 and 307(d)(7)(B) of the Clean Air Act (CAA) (42 U.S.C. 7412 and 7607(d)(7)(B)).

B. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated by this action are shown in Table 1 of this preamble.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

Source category	NESHAP	NAICS Code [1]
Miscellaneous Organic Chemical Manufacturing	40 CFR part 63, subpart FFFF	3251, 3252, 3253, 3254, 3255, 3256, and 3259, with several exceptions.

[1] North American Industry Classification System.

Table 1 of this preamble is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of these NESHAP, please contact the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal at this same website.

II. Background

On December 17, 2019, the EPA published a proposed rule in the **Federal Register** addressing the risk and technology review (RTR) for the Miscellaneous Organic Chemical Manufacturing NESHAP (MON), 40 CFR part 63, subpart FFFF (84 FR 69182). On August 12, 2020, after receiving and addressing public comments, the EPA finalized determinations pursuant to CAA sections 112(d)(6) and (f)(2) for the Miscellaneous Organic Chemical Manufacturing source category and amended the rule based on those determinations (85 FR 49084). The August 2020 final action, herein referred to as the ''2020 MON final rule,'' included amendments pursuant to the technology review for equipment leaks and heat exchange systems, and also amendments pursuant to the risk review to specifically address ethylene oxide emissions from storage tanks, process vents, and equipment leaks. In addition, the 2020 MON final rule corrected and clarified regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM, adding work practice standards for periods of SSM where appropriate, and clarifying regulatory provisions for certain vent control bypasses. The final action also added monitoring and operational requirements for flares that control ethylene oxide emissions and flares used to control emissions from processes that produce olefins and polyolefins, added provisions for electronic reporting of performance test results and other reports, and included other technical corrections to improve consistency and clarity.

In the 2020 MON final rule's risk assessment,[1] we calculated cancer risks using the EPA's IRIS inhalation unit risk estimate (URE) for ethylene oxide,[2] and the risk review included a determination that the risks for this source category under the current Maximum Achievable Control Technology (MACT) provisions were unacceptable due to ethylene oxide emissions. When risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level. As such, the EPA promulgated final amendments to the MON pursuant to CAA section 112(f)(2) that require control of ethylene oxide emissions for process vents, storage tanks, and equipment in ethylene oxide service. The 2020 MON final rule reduced risks to an acceptable level that also provides an ample margin of safety to protect public health. The final rule preamble stated that ''the EPA remains open to new and updated scientific information,'' and new dose-response values, such as those then being developed by the TCEQ (85 FR 49098). However, by the close of the public comment period for the proposed rulemaking (March 19, 2020), the TCEQ dose-response value had not yet been finalized and could not be considered in the final action.

Following promulgation of the 2020 MON final rule, the EPA received five separate petitions for reconsideration from four petitioners. The EPA received two petitions from the American Chemistry Council (ACC) (one petition dated October 2020, one dated December 2020), one from the TCEQ (dated October 2020), one from Squire Patton Boggs (US) LLP (submitted on behalf of Huntsman Petrochemical, LLC) (dated October 2020), and one from Earthjustice (submitted on behalf of RISE St. James, Louisiana Bucket Brigade, Louisiana Environmental Action Network, Texas Environmental Justice Advocacy Services (t.e.j.a.s.), Air Alliance Houston, Ohio Valley Environmental Coalition, Blue Ridge Environmental Defense League, Inc., Environmental Justice Health Alliance for Chemical Policy Reform, Sierra Club, Environmental Integrity Project, and Union of Concerned Scientists) (dated October 2020). Copies of the petitions are available in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

Three petitioners (ACC, TCEQ, Huntsman Petrochemical, LLC)

[1] Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0189.*

[2] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

requested the EPA reconsider the rule to reassess the risk assessment for the 2020 MON final rule using the TCEQ's alternative risk value for ethylene oxide instead of the EPA's 2016 IRIS value for ethylene oxide. These three petitioners further argued that the EPA's 2016 IRIS value for ethylene oxide is flawed, citing disagreement with the 2016 IRIS assessment's model selection and inclusion of breast cancer data. In their October 2020 petition, ACC argued that ''CAA Section 307(d)(7)(B) requires EPA to convene a reconsideration proceeding where (1) it was either impractical to raise an objection during the comment period or new information becomes available after the close of the comment period; and (2) such information is of central relevance to the outcome of the rule.'' Earthjustice did not raise a similar issue in their petition. Two petitioners (ACC and Earthjustice) raised other issues unrelated to the use of the IRIS value or TCEQ value for assessing risk from ethylene oxide emissions (see Docket ID No. EPA–HQ–OAR–2018–0746).

On June 22, 2021, the EPA sent letters to all the petitioners informing them that: (1) The EPA was granting reconsideration requests on two specific issues (described later in this section), (2) the EPA intended to issue a **Federal Register** document initiating a notice and comment rulemaking on the issues for which the Agency granted reconsideration, and (3) the EPA was continuing to review the other issues in the petitions for reconsideration and may choose to initiate reconsideration of additional issues in the future. Copies of the letters to petitioners are available in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

Pursuant to CAA section 307(d)(7)(B), the Agency granted reconsideration of the following aspects of the 2020 MON final rule: (1) The use of the EPA's IRIS value for ethylene oxide in assessing cancer risk for the source category, and (2) the use of the TCEQ risk value for ethylene oxide as an alternative risk value to the EPA's IRIS value for purposes of evaluating risk under CAA section 112(f)(2). Reconsideration was granted on these two topics on the following bases: The TCEQ risk value for ethylene oxide was finalized after the comment period for the proposed MON rulemaking closed, and the 2020 MON final rule preamble stated that the EPA remains open to new and updated scientific information, such as the TCEQ value; and because the risk posed by ethylene oxide is of central relevance to the EPA's determination that the risks from sources in the Miscellaneous Organic Chemical Manufacturing source category remaining after imposition of the then-current CAA section 112(d)(2) MACT standards were unacceptable and that more stringent standards are required. Because the criteria for mandatory reconsideration under CAA section 307(d)(7)(B) have been satisfied, the Agency is publishing this proposed reconsideration action in the **Federal Register** and requesting public comment on the issues discussed in this action. The EPA is seeking comment only on the issues subject to mandatory reconsideration and discussed in this proposed rule. The Agency will not respond to any comments addressing other issues raised by petitioners related to the 2020 MON final rule, or the EPA's December 13, 2021 response [3] to the Request for Correction (RFC) [4] of the IRIS value for ethylene oxide that was submitted to the EPA by petitioner ACC under the Information Quality Act, Public Law 106–554 (IQA). As discussed in section III.B of this preamble, the ACC requested correction of the ethylene oxide information in the EPA's most recent update to the National Air Toxics Assessment (NATA) released on August 22, 2018. In the EPA's response to the RFC, the EPA found that the RFC did not identify a need for correction in the 2016 ethylene oxide IRIS Assessment and determined that the inhalation URE derived in the 2016 ethylene oxide IRIS Assessment was the appropriate human health value to use for ethylene oxide in the 2014 NATA. The EPA's response to the RFC noted that the EPA's use of the IRIS value in CAA rulemakings would be addressed in the reconsideration of the 2020 MON final rule, and that the review would include consideration of additional information presented in comments on the 2020 MON rule that were not included in the 2018 RFC and addressed in the EPA's response to the RFC. As such, we are not reconsidering comments on the EPA's reliance upon the National Institute for Occupational Safety and Health (NIOSH) worker exposure studies, selection of dose-response models, and consideration of endogenous sources (*i.e.,* what the body produces) of ethylene oxide that were previously addressed in the response to ACC's RFC.

III. Reconsideration Issues and Request for Public Comments

The EPA is proposing to take comment on the two selected issues raised in the petitions for reconsideration as described in sections III.A. and III.B. below.

A. Use of the EPA's IRIS Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

The EPA's IRIS program was created to provide an internal Agency database of human health effects that may result from chronic exposure to chemicals found in the environment to which the public might be exposed. The IRIS database is intended to be used by the EPA's program and regional offices in risk assessments to inform decision making.[5] The development of IRIS values includes a robust peer-review, beginning with internal reviews to reach consensus within the Agency on the scientific positions, followed by external federal agency review, an opportunity for public review and comment, and an independent, external peer-review by the EPA's Science Advisory Board (SAB).[6] During this process, the EPA considers and responds to comments received from the public and the SAB, and revises the assessment to ensure that the best available science is represented.

During development of the 2020 MON final rule, the EPA used the 2016 IRIS cancer risk value for ethylene oxide [7] in the risk review. The EPA received and responded to numerous public comments on the use of the IRIS value in the 2020 MON final rule. A summary of these comments and responses is available in the preamble of the 2020

[3] U.S. EPA. EPA's Response to American Chemistry Council (ACC)'s Request for Correction to the IRIS Value for Ethylene Oxide (EtO) used in the National Air Toxics Assessment (NATA) in 2018. December 13, 2021. Available at: *https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[4] American Chemistry Council. Request for Correction under the Information Quality Act: 2014 National Air Toxics Assessment (NATA). September 20, 2018. Available at: *https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[5] U.S. EPA. Framework for Human Health Risk Assessment to Inform Decision Making. EPA/100/R–14/001. April 2014. Available at *https://www.epa.gov/sites/default/files/2014-12/documents/hhra-framework-final-2014.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[6] U.S. EPA. Process for Developing IRIS Health Assessments. Integrated Risk Information System (IRIS). *https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process.*

[7] The age-adjusted inhalation URE for ethylene oxide is 0.005 per $\mu g/m^3$. The URE is the upper-bound additional lifetime cancer risk estimated to result from continuous (24 hours/day) lifetime (70 years) exposure to ethylene oxide at a concentration of 1 $\mu g/m^3$ in air. Because ethylene oxide is mutagenic (*i.e.,* damages DNA), an age-dependent adjustment factor was applied to account for childhood exposures.

MON final rule (85 FR 49084; August 12, 2020) and also in the ''Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing'' document in the docket for this rulemaking.[8]

For CAA section 112(f)(2) risk reviews, the EPA performs health risk assessments for the hazardous air pollutants (HAP) that are emitted from the source category after imposition of MACT standards under CAA section 112(d)(2). Consistent with the purpose of the IRIS database for use by the EPA's program and regional offices in risk assessments and the advice from the SAB, the ''Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule'' in the docket for this rulemaking[9] described that the preferred source of chronic dose-response data is the IRIS database. If the EPA's IRIS program does not have an up-to-date hazard and/or dose-response assessment for a HAP, the EPA considers publicly available assessments that have been developed by other government agencies in a manner that is conceptually similar to the EPA's approach. This includes consistency with the EPA's risk assessment guidelines, incorporation of an independent external peer review, inclusion of a public review period, and use of the best available science with respect to dose-response information.

Application of this approach generally results in the following priority order for sources of risk values such as an inhalation URE: (1) U.S. EPA IRIS, (2) Agency for Toxic Substances and Disease Registry (ATSDR), (3) California EPA, and (4) other sources. Documentation of this approach, as applied in the CAA section 112(f)(2) reviews, is in the EPA report titled ''Risk and Technology (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board: Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing''.[10] This approach is also documented in the risk assessment technical support document for each RTR NESHAP rulemaking and is included in the rulemaking docket for this action.[11] [12]

This approach was presented to the SAB in 2009. In a May 7, 2010, memo[13] to the EPA Administrator regarding review of the EPA's RTR assessment methodologies, the SAB panel supported the EPA's approach to selecting dose-response chronic toxicity values. In the same memo, they also noted that: ''The preferred database for chronic dose-response data is and should be the IRIS database. However, some chemicals of interest do not have IRIS values, and values for other chemicals have not been reviewed recently. The Panel urges the Agency to address these gaps and provide the resources necessary to maintain the updating process. Additional sources of data may also be considered if they have undergone adequate and rigorous scientific peer review.'' *Id.* at 5.

In the 2020 MON final rule, the EPA followed this documented approach in selecting the 2016 EPA IRIS value for ethylene oxide for use in the risk review. We have carefully reviewed the three petitioners' comments that the 2016 IRIS value for ethylene oxide should not have been used, but after careful consideration of the issues raised, we have determined that these petitioners have not identified a basis for changing our approach to the risk assessment in the 2020 MON final rule. The substantive arguments raised by these petitioners regarding the 2016 IRIS value have been addressed in the EPA's response to the RFC, in the 2020 MON final rule's preamble (85 FR 49084; August 12, 2020), and in the response to comment document[14] for the 2020 MON final rule; beyond these alleged flaws in the 2016 IRIS value, these petitioners have presented no new arguments for why the EPA should not follow the documented approach for selecting risk values. The EPA proposes to not change its decision to use the IRIS inhalation URE for ethylene oxide in the 2020 MON final rule. Consequently, the EPA is proposing no changes to our risk assessment for the 2020 MON final rule.

B. Use of the TCEQ Risk Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

During development of the 2020 MON final rule, the EPA received and responded to numerous public comments related to the use of the TCEQ's risk value for ethylene oxide as an alternative to the EPA's IRIS value in the 2020 MON risk assessment. TCEQ submitted its draft Development Support Document (DSD), which included the dose-response analysis underlying TCEQ's draft cancer risk value, as a comment during the 2020 MON rulemaking's comment period. Because the TCEQ risk value was not final until after the close of the comment period, the EPA did not directly assess the draft DSD from TCEQ in our final rule; however, the EPA received and addressed public comments from other groups (*e.g.,* ACC) that included the same analytical approaches utilized by TCEQ. A summary of these comments and responses is available in the 2020 MON final rule's preamble (85 FR 49084; August 12, 2020) and in the response to comment document[15] for the 2020 MON final rule. In this action, the EPA reaffirms those responses in support of its decision to use the IRIS inhalation URE in the 2020 MON final rule.

As part of this proposed reconsideration of the 2020 MON final rule, the EPA reviewed the final TCEQ ethylene oxide DSD, which TCEQ referenced in its petition for reconsideration, including the assertion that the final DSD contained ''additional scientific analyses''. Based on this review, we have determined that TCEQ

[8] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200*.

[9] Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0189*.

[10] U.S. EPA. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing, June 2009.* EPA–452/R–09–006. Available at *https://www3.epa.gov/airtoxics/rrisk/rtrpg.html* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[11] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200*.

[12] Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0189*.

[13] SAB. Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, *Review of EPA's draft entitled, ''Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing.* Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[14] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200*.

[15] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200*.

did not submit new data for the EPA's consideration that would cause us to use the final TCEQ cancer risk value instead of the IRIS cancer risk value for the MON risk review. Rather, TCEQ has pursued a different approach to analyzing the same NIOSH occupational exposure dataset that is the basis of the 2016 IRIS cancer risk value.

By using this approach, TCEQ estimated a risk value for ethylene oxide that is 2000-fold lower than that of the IRIS risk value.[16] TCEQ's analytical approach (*i.e.,* modeling mortality using a Cox proportional hazards model) closely mirrors the approach by Valdez-Flores (2010)[17] previously presented by other public commenters in the 2020 MON final rule, and which the EPA addressed in both its response to comments document[18] and its December 13, 2021 response[19] to the ACC's 2018 RFC regarding the EPA's use of the IRIS value for ethylene oxide. In addition to pursuing an analytical approach similar to that used by Valdez-Flores (2010), TCEQ went a step further and excluded women from their analysis. This exclusion included all lymphoid cancers in women, as well as the exclusion of breast cancer as an endpoint. Although modeling cancer mortality (instead of cancer incidence, which the EPA modeled) and excluding women from the lymphoid cancer analysis impacted the final URE value, the 2000-fold difference in the IRIS versus TCEQ risk values is driven primarily by two major differences: (1) TCEQ selected a different statistical model to represent the occupational exposure data; and (2) TCEQ excluded breast cancer from the derivation of a cancer risk value based on the claim that there is insufficient weight of evidence that ethylene oxide exposure causes breast cancer.

The questions of the appropriate dose-response model to use to evaluate the risk of ethylene oxide and the strength of the evidence linking ethylene oxide exposure to breast cancer were addressed in the 2016 ethylene oxide IRIS assessment. These questions were raised again in comments on the 2020 MON final rule and responded to in both the preamble (85 FR 49084; August 12, 2020) and associated response to comments document[18] for the 2020 MON final rule. Briefly, these responses note that the EPA's 2016 IRIS risk value for ethylene oxide is based on a statistical model selected to best represent the available data on cancers in workers exposed to ethylene oxide. This model, a two-piece linear spline model, was selected after extensive review by the EPA and the SAB. The Agency and the SAB[20][21] carefully considered and evaluated multiple alternative models, including a Cox proportional hazards regression model similar to that used by TCEQ. In its response to the SAB's recommendations, the EPA noted: ''The EPA has followed the SAB's recommendations for model selection. Model selection for both the breast cancer incidence (see section 4.1.2.3) and lymphoid cancer (see section 4.1.1.2) data prioritizes functional forms that allow more local fits in the low-exposure range (*e.g.,* spline models), relies less on AIC,[22] and includes consideration of biological plausibility . . .'' (IRIS, 2016, Appendix I, p. I–3). As such, in the 2016 ethylene oxide IRIS assessment, the EPA selected a model that best represented potential general population exposures, making it align well with the purpose of the risk assessment in the 2020 MON final rule, which sought to assess general risk exposure to the public.

Additionally, the EPA considered the weight of evidence regarding the risk of breast cancer from exposure to ethylene oxide in the IRIS process. In the 2016 IRIS ethylene oxide assessment, the EPA determined that the available epidemiological evidence for a causal relationship between ethylene oxide exposure and breast cancer was strong, and there were sufficient data to include breast cancer in the derivation of the URE. The SAB supported this determination. Comments on the evidence for breast cancer as an endpoint following ethylene oxide exposure were also addressed during the review process for the IRIS ethylene oxide assessment. For example, in response to a public comment on the IRIS 2013 draft claiming that the evidence for breast cancer is too weak to rely on in setting the URE, the EPA responded:

''Although the epidemiological database for breast cancer is more limited (*i.e.,* few studies with sufficient numbers of female breast cancer cases) than that for lymphohematopoietic cancers, the EPA determined that the available evidence is sufficient to consider breast cancer a potential hazard from ethylene oxide exposure . . .The 2007 SAB panel did not object to the derivation of unit risk estimates based on the available breast cancer evidence.'' (IRIS, 2016, Appendix K, p. K–3).[23] The IRIS cancer risk value is representative of potential health risks to the general population because it reflects the combined cancer risk of developing lymphoid cancers in all people, and breast cancer in women.

After careful consideration of the TCEQ DSD and material provided in the petitions for reconsideration that requested the EPA use TCEQ's final cancer risk value, the EPA is proposing to determine that the TCEQ assessment and the petitions for reconsideration do not provide a scientifically supportable basis for relying on the URE developed by TCEQ to assess the residual risk for sources in the 2020 MON final rule. No new studies or other information have been identified by TCEQ or the petitioners requesting reconsideration that would call into question the conclusions in the 2016 IRIS ethylene oxide assessment or suggest that TCEQ's URE provides a better estimate of the risk of exposure from ethylene oxide. The 2016 ethylene oxide IRIS

[16] TCEQ's age-adjusted URE is 2.3×10^{-6} per µg/m^3.

[17] Valdez-Flores C, Sielken RL Jr, Teta MJ. 2010. Quantitative cancer risk assessment based on NIOSH and UCC epidemiological data for workers exposed to ethylene oxide. Regul Toxicol Pharmacol, 56(3): 312–20.

[18] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200.*

[19] U.S. EPA. EPA's Response to American Chemistry Council (ACC)'s Request for Correction to the IRIS Value for Ethylene Oxide (EtO) used in the National Air Toxics Assessment (NATA) in 2018. December 13, 2021. Available at: *https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[20] SAB. (2007). *Science Advisory Board Review of Office of Research and Development (ORD) draft assessment entitled, ''Evaluation of the Carcinogenicity of Ethylene Oxide'' [EPA Report].* (EPA–SAB–08–004). Washington, DC: U.S. EPA, SAB. Available at: *http://yosemite.epa.gov/sab/sabproduct.nsf/368203f97a15308a852574ba005bbd01/5D661BC118B527A3852573B80068C97B/$File/EPA-SAB-08-004-unsigned.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[21] SAB. (2015). *Science Advisory Board Review of the EPA's Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide: Revised external review draft—August 2014 [EPA Report].* (EPA–SAB–15–012). Washington, DC: U.S. EPA, SAB. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/BD2B2DB4F84146A585257E9A0070E655/$File/EPA-SAB-15-012+unsigned.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[22] The Akaike information criterion (AIC) is a mathematical model for evaluating how well a model fits the underlying dataset from which it was generated.

[23] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

assessment remains the best available science, and the EPA proposes to reaffirm its decision to use the IRIS inhalation URE in the 2020 MON final rule.

IV. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

We estimate that, as of November 6, 2018, there were 201 MON facilities, nine of which reported ethylene oxide emissions to the 2014 National Emissions Inventory. However, as the EPA is not proposing any changes to the regulatory text or regulatory requirements in this action, we do not anticipate that any sources will be affected by this reconsideration. A complete list of known MON facilities is available in Appendix 1 of the document, Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule, which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0011).

B. What are the air quality impacts?

The EPA does not project any air quality impacts associated with this action because this action does not propose any changes to the standards or other requirements on affected sources.

C. What are the cost impacts?

The EPA does not project any incremental costs associated with this action because it does not propose any changes to the standards or other requirements on affected sources.

D. What are the economic impacts?

The EPA does not project any economic impacts because there are no incremental costs associated with this action.

E. What are the benefits?

The EPA does not project any incremental benefits associated with this action because it does not propose any changes to the standards or other requirements on affected sources.

V. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was therefore not submitted to 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.

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, the 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 if the rule has no net burden on the small entities subject to the rule. As we are not proposing any changes to the regulatory text or regulatory requirements, we do not anticipate any economic impacts resulting from this action. We have 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 proposes 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. None of the MON facilities that have been identified as being affected by this action are owned or operated by tribal governments or located within tribal lands within a 10 mile radius. Thus, Executive Order 13175 does 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 because it is not economically significant as defined in Executive Order 12866, and because this action does not present any changes to the rule that would affect environmental health or safety risks, including those that would present a disproportionate risk to children.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This rulemaking does not involve technical standards.

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

The EPA believes that this action 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 regulatory action acts to clarify the language in the preamble of a previously promulgated regulatory action and does not have any impact on human health or the environment.

Michael S. Regan,

Administrator.

[FR Doc. 2022–01923 Filed 2–3–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 22–39; RM–11917; DA 22–87; FR ID 69837]

Television Broadcasting Services Billings, Montana

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Federal Communication Commission (Commission) has before it a petition for rulemaking filed by Scripps Broadcasting Holdings LCC (Petitioner), the licensee of WTVQ–TV, channel 10, Billings, Montana. The

Petitioner requests the substitution of channel 20 for channel 10 at in the Table of Allotments.

DATES: Comments must be filed on or before March 7, 2022 and reply comments on or before March 21, 2022.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Christina A. Burrow, Esq., Cooley LLP, 1299 Pennsylvania Avenue NW, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647; or Joyce Bernstein, Media Bureau, at *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: In support of its channel substitution request, the Petitioner states that the Commission has recognized that very high frequency (VHF) channels have certain characteristics that pose challenges for their use in providing digital television service and the station has received many complaints from viewers unable to receive a reliable signal on channel 10. An analysis using the Commission's *TVStudy* software tool indicates that KTVQ's move from channel 10 to channel 20 is predicted to create a small area where approximately 3,624 persons are predicted to lose service, but that the loss area, is partially overlapped by the noise limited contours of Scripps' owned TV translator stations K15LB–D, Red Lodge, Montana, and K28ON–D, Castle Rock, Montana, both of which carry the CBS network programming aired by KTVQ. Accordingly, only 483 persons would lose CBS service if KTVQ moves to channel 20, which Petitioner argues is *de minimis.* In addition, the Engineering Statement shows that the loss area is also partially overlapped by the noise limited contours of KSVI (ABC) and KULR (NBC), Billings, Montana; KHMT (FOX), Hardin, Montana; and KSGW (ABC/FOX), Sheridan, Wyoming. Thus, viewers in the loss area will continue to have access to major network programming.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 22–39; RM–11917; DA 22—87, adopted January 26, 2022, and released January 26, 2022. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer & Government Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a notice of proposed rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in § 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a).

See §§ 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622(j), amend the Table of Allotments under Montana by revising the entry for Billings to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(j) * * *

Community	Channel No.
* * * * *	
MONTANA	
* * * * *	
Billings	11, *16, 18, 20
* * * * *	

[FR Doc. 2022–02337 Filed 2–3–22; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 216 and 300

[Docket No. 220128–0036]

RIN 0648–BK88

International Fisheries; Pacific Tuna Fisheries; Purse Seine Observer Exemptions in the Eastern Pacific Ocean

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations under the authority of the Marine Mammal Protection Act (MMPA) and the Tuna Conventions Act (TCA) of 1950, as amended, to allow NMFS to issue temporary exemptions from purse seine observer requirements in the eastern Pacific Ocean (EPO) in accordance with procedures adopted by Parties to the Agreement on the International Dolphin Conservation Program (AIDCP) and members of the Inter-American Tropical Tuna Commission (IATTC). This proposed rule is necessary for the continuity of fishing activities for large U.S. purse seine vessels and for the United States to satisfy its obligations as a member of the IATTC.

DATES: Comments on the proposed rule must be submitted in writing by March 7, 2022.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2021–0111, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter ''NOAA–NMFS–2021–0111'' in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to William Stahnke, NMFS West Coast Region (WCR), Long Beach Office, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802. Include the identifier ''NOAA–NMFS–2021–0111'' in the comments.

Instructions: Comments must be submitted by one of the above methods

to ensure they are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of supporting documents that were prepared for this proposed rule, including the Regulatory Impact Review, are available via the Federal e-Rulemaking Portal: *www.regulations.gov,* docket NOAA–NMFS–2021–0111, or contact William Stahnke, NMFS WCR, Long Beach Office, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, or *WCR.HMS@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: William Stahnke, NMFS WCR, at (562) 980–4088.

SUPPLEMENTARY INFORMATION:

Background on the AIDCP and IATTC

The AIDCP has been ratified or acceded by 14 countries, including the United States, and is applied provisionally by another two. Among the objectives of the AIDCP are to reduce dolphin mortalities and ensure the long-term sustainability of the tuna stocks within the AIDCP Agreement Area.[1] The full text of the AIDCP is available online at: *https://www.iattc.org/PDFFiles/AIDCP/_English/AIDCP.pdf.*

The United States is a member of the IATTC, which was established under the 1949 Convention for the Establishment of an Inter-American Tropical Tuna Commission (1949 Convention). The 1949 Convention was updated by the Convention for the Strengthening of the IATTC Established by the 1949 Convention between the United States of America and the Republic of Costa Rica (Antigua Convention). The full text of the Antigua Convention is available online at: *https://www.iattc.org/PDFFiles/IATTC-Instruments/_English/IATTC_Antigua_Convention%20vJun%202003.vpdf.*

The IATTC consists of 21 member nations and five cooperating non-member nations. The IATTC facilitates scientific research, as well as the conservation and management, of tuna and tuna-like species in the IATTC Convention Area.[2] The IATTC maintains a scientific research and fishery monitoring program and regularly assesses the status of tuna, sharks, and billfish stocks in the IATTC Convention Area to determine appropriate catch limits and other measures deemed necessary to promote sustainable fisheries and prevent the overexploitation of these stocks.

International Obligations of the United States Under the Antigua Convention and AIDCP

As a Party to the Antigua Convention and AIDCP and a Member of the IATTC, the United States is legally bound to implement decisions of the IATTC under the Tuna Conventions Act (16 U.S.C. 951 *et seq.*) and decisions of the Parties to the AIDCP under the Marine Mammal Protection Act (16 U.S.C. 1361 *et seq.*). The Tuna Conventions Act directs the Secretary of Commerce, in consultation with the Secretary of State and, with respect to enforcement measures, the U.S. Coast Guard, to promulgate such regulations as may be necessary to carry out the United States' obligations under the Antigua Convention, including recommendations and decisions adopted by the IATTC. The authority of the Secretary of Commerce to promulgate such regulations has been delegated to NMFS. The MMPA directs the Secretary of Commerce to issue regulations, and revise those regulations as may be appropriate, to implement the International Dolphin Conservation Program. As with the TCA, the authority of the Secretary of Commerce to promulgate such regulations has been delegated to NMFS.

AIDCP and IATTC Observer Program and U.S. Observer Requirements

U.S. large purse seine vessels (*i.e.,* those greater than 400 short ton carrying capacity) fishing for tuna in the EPO are subject to 100 percent observer coverage obligations under Annex II, paragraph 2 of the AIDCP and IATTC Resolution C–09–04, *Resolution on the International Dolphin Conservation Program.* The United States implemented this requirement for 100 percent observer coverage into domestic regulation at 50 CFR 216.24(e)(1), which requires vessel permit holders to allow an authorized observer to accompany the vessel on all fishing trips in the Eastern Tropical Pacific (ETP) for the purpose of collecting information pertaining to research and observing operations and prohibits vessels that fail to carry an observer in accordance with these requirements from engaging in fishing operations. The United States does not have its own national observer program for the large tuna purse seine fishery and relies solely on the AIDCP/IATTC program to place observers on U.S. large purse seine vessels. The observers are typically foreign nationals that board U.S. vessels at ports throughout Central and South America, as well as American Samoa.

AIDCP and IATTC Agreement for Exemptions and NMFS Emergency Observer Exemption Rule

On April 16, 2020, the IATTC issued a memorandum (Ref.: 0173–420)[3] indicating that the AIDCP Parties and the IATTC Members adopted procedures to provide for the temporary exemption, on a case-by-case basis, from purse seine observer requirements in the EPO for each vessel and trip where it is not possible to place an observer due to operational and logistical constraints arising from actions taken by governments or organizations to safeguard health in response to the COVID–19 Pandemic. Under these exemption procedures, owners and operators of vessels must continue requesting the placement of observers in accordance with pre-existing procedures. An AIDCP/IATTC exemption is considered granted when the IATTC Director, or the head of the field office and the national observer program office of AIDCP Parties, certify the unavailability of an observer for the vessel. These procedures were set to expire June 1, 2020, but the AIDCP/IATTC issued several subsequent memoranda extending the procedures, most recently until March 31, 2022 (0564–420; December 16, 2021), and they are expected to be extended further. The current AIDCP/IATTC exemption procedures are discussed in greater detail in the next section of this preamble.

In addition to the AIDCP/IATTC procedures, NMFS needed authority to provide exemptions from domestic regulations requiring observer coverage. On March 27, 2020, NMFS published a

[1] Defined as waters of the EPO within the area bounded by the west coast of the Americas and by 50° N latitude, 150° W longitude, and 50° S latitude.

[2] Defined as waters of the EPO within the area bounded by the west coast of the Americas and by 50° N latitude, 150° W longitude, and 50° S latitude.

[3] Copies of IATTC Memo #0173–420 as well as the original NMFS exemption procedures can be found in the docket for this rulemaking.

temporary rule for an emergency action in response to the COVID–19 Pandemic (85 FR 17285) that provides the authority to waive observer coverage requirements implemented under certain statutes, including the MMPA and TCA (''NMFS Emergency Rule''). That NMFS Emergency Rule permits NMFS to waive observer coverage requirements if:

(1) Placing an observer conflicts with travel restrictions or other requirements addressing COVID–19 related concerns issued by local, state, or national governments, or the private companies that deploy observers pursuant to NMFS regulations; or

(2) No qualified observer(s) are available for placement due to health, safety, or training issues related to COVID–19.

That temporary NMFS Emergency Rule was extended and is currently in effect until March 26, 2022, or until the Secretary of Health and Human Services determines that the COVID–19 Pandemic is no longer a public health emergency, whichever is earlier (March 29, 2021; 86 FR 16307). Pursuant to the NMFS Emergency Rule, and in accordance with exemption procedures adopted by the AIDCP/IATTC, NMFS West Coast Region (WCR) established a process, subject to revocation or extension as circumstances warrant, for issuing temporary exemptions on an individual basis to the U.S. regulatory requirements for observer requirements for large U.S. tuna purse seine vessels in the EPO. This process, which NMFS is proposing to maintain under the proposed rule, is discussed in greater detail in the next section of this preamble.

Proposed Amendment to 50 CFR 216.24(e) To Allow for Exemptions From Purse Seine Observer Requirements in the EPO

Though difficult to predict, NMFS expects travel restrictions will likely continue in American Samoa and other port States where observers are placed on purse seine vessels beyond March 26, 2022. As noted, the AIDCP/IATTC exemptions procedures have been extended until March 31, 2022, and are expected to be extended further. However, the temporary NMFS Emergency Rule that provides the United States domestic authority to waive observer coverage for large EPO purse seine vessels will expire on March 26, 2022. After this time, NMFS will no longer have the authority to issue exemptions from observer requirements to large purse seine vessels fishing in the EPO. Without the authority to issue observer exemptions, the United States would likely be the only AIDCP Party and IATTC Member unable to issue these exemptions to its purse seine vessels. This proposed rule is therefore necessary to allow NMFS to continue issuing temporary exemptions from the observer requirements beyond the NMFS Emergency Rule expiration date in March 2022 in accordance with continuing AIDCP/IATTC exemption procedures and, potentially, in accordance with exemption procedures adopted in the future. Because the AIDCP contains an unqualified requirement for 100 percent observer coverage, NMFS anticipates that the AIDCP/IATTC will only adopt exemption procedures in the future under emergency circumstances similar to the COVID–19 pandemic and that those procedures would be similarly limited to single fishing trips for which it would be impossible to place an observer on a vessel.

This rule is proposed under the authorities of the MMPA and TCA. This rule would amend § 216.24(e)(1) to add a provision that will allow NMFS to issue temporary exemptions from purse seine observer requirements, on a case-by-case basis, in accordance with procedures adopted by the Parties to the AIDCP and Members of the IATTC. These temporary exemptions would apply to U.S. large purse seine vessels that are used to catch tropical tuna in the IATTC Convention Area and would exempt a single vessel from the requirement to carry an observer during a single fishing trip, provided the vessel complies with AIDCP/IATTC exemption procedures and with other applicable regulations and requirements. Although the proposed provision would not expire, it would only be applicable for the duration that AIDCP and IATTC observer exemption procedures are effective. In other words, the proposed provision would only give NMFS the authority to grant an exemption: (1) If the Parties to the AIDCP and Members of the IATTC have collectively agreed to adopt procedures for exempting observer coverage requirements under certain emergency circumstances; and (2) in accordance with the specific procedures adopted by AIDCP/IATTC for granting those exemptions.

NMFS will notify the affected fleet via email when the current AIDCP/IATTC emergency exemption procedures are no longer in effect. NMFS will also notify the affected fleet via email and the public by publication of a notice in the **Federal Register** if new exemption procedures are adopted by the Parties to the AIDCP and Members of the IATTC. New exemptions would not be issued by NMFS when AIDCP/IATTC exemption procedures are not in effect and exemptions issued by NMFS while AIDCP/IATTC exemption procedures are in effect would only be effective for as long as the AIDCP/IATTC procedures remain in effect.

Process for Obtaining an Observer Exemption From the IATTC

As previously noted, the AIDCP Parties and the IATTC Members adopted procedures for the temporary exemption, on a case-by-case basis, of the requirement to carry an observer for trips where it is not possible to place an observer on a vessel. The process for a vessel to be granted an exemption from the IATTC is outlined below:

- Vessel owners/operators planning a fishing trip in the EPO are to contact the IATTC Director and Observer Coordinator to request an observer.
- If the IATTC Director, or the head of the field office and the national program office, certifies, in coordination with Flag State Authorities, that it is not possible to place an observer on the vessel, then an exemption from AIDCP observer requirements will be considered granted for the fishing trip.

Process for Obtaining an Observer Exemption From NMFS

In addition, U.S. large purse seine vessels must also obtain from NMFS WCR an individual exemption from regulatory observer coverage requirements. As discussed previously, NMFS has been issuing those exemptions under the authority of the NMFS Emergency Rule; however, if finalized, this proposed rule would provide NMFS the authority to continue issuing such exemptions while AIDCP/IATTC exemption procedures are in effect. NMFS would continue using the existing process for a U.S. vessel to obtain an exemption from domestic regulations, as outlined below:

- Once NMFS West Coast Region receives certification from the IATTC or the vessel owner/operator that an exemption has been granted, NMFS will confirm that the vessel owner/operator meets the criteria set forth in the AIDCP/IATTC exemption procedures.
- If the criteria are met, NMFS will issue the permit holder a letter documenting that the requirement to carry an observer has been exempted for that vessel trip.
- A NMFS observer exemption may be requested from the NMFS West Coast Region, Sustainable Fisheries Division, Highly Migratory Species (HMS) Branch, via *WCR.HMS@noaa.gov.*

NMFS anticipates working in coordination with the IATTC and being able to provide individual vessel

exemptions without significant delay to U.S. large purse seine vessels. Any changes to these procedures will be notified by email directly and/or via relevant email distribution lists to vessel owners, operators, and permit holders.

Dolphin-Safe Requirements

It should be noted that although these proposed regulations will allow NMFS to waive the regulatory requirements in § 216.24(e)(1) to carry an observer, tuna caught in the ETP on a trip without an AIDCP-approved observer will be ineligible for a United States dolphin-safe label or an AIDCP Dolphin-Safe Tuna Certificate. With respect to the U.S. dolphin-safe label, any tuna harvested by large purse seine vessels fishing in the ETP is subject to U.S. dolphin-safe labeling requirements at 50 CFR part 216, subpart H, and also subject to the authority of the International Dolphin Conservation Program Act (ICDPA; 16 U.S.C. 1417). Without an AIDCP-approved observer on a fishing trip (even with an observer exemption), the Tuna Tracking Forms (TTFs) cannot be completed by an observer for that trip and, thus, the tuna would be ineligible for a dolphin-safe label. TTFs are necessary for the issuance of the U.S.-required IDCP-member nation certification to accompany the NOAA Form 370 for tuna harvested by large purse seine vessels in the ETP. However, such tuna harvested in the ETP without an observer may still be legally sold in the United States as non-dolphin-safe, provided it was harvested in accordance with other relevant requirements.

With respect to the AIDCP Dolphin-Safe Tuna Certificate, it should also be noted that the AIDCP Parties did not waive the requirement for the observer's role in verifying the dolphin-safe status of the catches under the AIDCP Dolphin-Safe Tuna Certification Program. Therefore, any trip by a vessel of an AIDCP Party that is made without an observer would not have valid TTFs and, thus, no valid AIDCP Dolphin-Safe Tuna Certificate can be issued by a Party for any catches made on that particular fishing trip.

Proposed Amendments to 50 CFR 300.24 and 300.25 To Incorporate Existing Purse Seine Observer Requirements Into the Regulations That Govern Eastern Pacific Tuna Fisheries

As noted earlier, the regulatory requirement for large purse seine vessels to carry observers during fishing operations in the EPO are found in 50 CFR part 216, which contains regulations governing the taking and importing of marine mammals. This proposed rule would incorporate that requirement into 50 CFR part 300, subpart C, which contains regulations governing eastern Pacific tuna fisheries. Specifically, NMFS proposes to add to § 300.25, *Fisheries Management,* a provision that re-states, and cross-references to, the existing observer coverage requirement in § 216.24(e)(1). This provision would clarify that the requirements in § 216.24(e)(1) apply within the IATTC Convention Area. NMFS also proposes to add to § 300.24(n) a prohibition against operating a large purse seine vessel in the IATTC Convention Area in contravention of applicable observer requirements.

Classification

The NMFS Assistant Administrator has determined that this proposed rule is consistent with the Marine Mammal Protection Act, Tuna Conventions Act of 1950, and other applicable laws.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

There are no new collection-of-information requirements associated with this action that are subject to the Paperwork Reduction Act (PRA), and the existing collection-of-information requirements still apply under Office of Management and Budget (OMB) Control Numbers 0648–0148 (West Coast Region Pacific Tuna Fisheries Logbook, Fish Aggregating Device Form, and Observer Safety Reporting) and 0648–0335 (Fisheries Certificate of Origin). Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to 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. All currently approved NOAA collections of information may be viewed at: *https://www.reginfo.gov/public/do/PRAMain.*

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The rationale for the certification is provided in the following paragraphs.

As previously mentioned, NMFS expects that travel restrictions due to the COVID–19 pandemic will likely continue in American Samoa and foreign ports where observers are placed on purse seine vessels into the foreseeable future. NMFS also expects that the AIDCP/IATTC will extend their observer exemptions procedures beyond the current March 31, 2022, expiration date. With the NMFS Emergency Rule that provides the United States domestic authority to waive observer coverage for large EPO purse seine vessels expiring on March 26, 2022, NMFS will no longer have the authority to issue exemptions from observer requirements to large purse seine vessels fishing in the or EPO after that date. This proposed rule will allow NMFS to continue issuing temporary exemptions from the observer requirements. The absence of this proposed rule would result in NMFS being unable to issue exemptions in cases where no observer is available, preventing U.S. large purse seine vessels from legally fishing, thereby decreasing fishing opportunities and putting the U.S. fleet at a competitive disadvantage.

The United States Small Business Administration (SBA) defines a ''small business'' (or ''small entities'') as one with annual revenue that meets or is below an established size standard. NMFS has established that the small business size standard for all businesses primarily engaged in the commercial fishing industry (NAICS 11411) for Regulatory Flexibility Act (RFA) compliance purposes (80 FR 81194, December 29, 2015), is $11 million in annual gross receipts. The standard is to be used in place of the U.S. SBA standards of $20.5 million, $5.5 million, and $7.5 million for the finfish (NAICS 114111), shellfish (NAICS 114112), and other marine fishing (NAICS 114119) sectors, respectively, of the U.S. commercial fishing industry.

The entities directly affected by the actions of this proposed action are U.S. large (*i.e.,* well volume greater than 425 cubic meters) tuna purse seine vessels that are required to carry fisheries observers, pursuant to the AIDCP and U.S. regulations at § 216.24(e). Per the $11 million size standard, these purse seine vessels are both large and small businesses.

Estimates of ex-vessel revenues for large U.S. purse seine vessels fishing in the IATTC Convention Area before 2015 have been confidential and may not be publicly disclosed because of the small number of vessels in the fishery. However, beginning in 2015, more than three large purse seine vessels fished either exclusively in the EPO, or fished in both the EPO and WCPO. Thus, information from 2015 to 2020 is not confidential.

Ex-vessel price information specific to individual large U.S. purse seine vessels are not available to NMFS because these

vessels did not land on the U.S. West Coast and the cannery receipts are not available through the IATTC. However, Regional Purse Seine Logbook (RPL) data from NMFS Pacific Islands Fisheries Science Center (PIFSC), and observer data from the IATTC may be used as a proxy for fish landings by large U.S. purse seiners, in lieu of cannery receipts. Since neither gross receipts nor ex-vessel price information specific to individual fishing vessels are available to NMFS, NMFS applied indicative regional cannery prices—as approximations of ex-vessel prices—to annual catches of individual vessels obtained from RPLs and IATTC observer data, to estimate the vessels' annual receipts. Indicative regional cannery prices are available through 2020 (developed by the Pacific Islands Forum Fisheries Agency; available at (*https://www.ffa.int/node/425*). NMFS estimated vessels' annual receipts during 2019–2020. Using this approach, NMFS estimates that among the affected vessels, the range in annual average receipts in 2019–2020 was $400,000 to $15 million with an average of approximately $8 million. U.S. EPO purse seine vessels that carry observers in the IATTC Convention Area are both large and small entities. While vessels often fluctuate from year to year as being classified as a large or small entity, the majority of large U.S. purse seine vessels typically fall under the small entity category.

As of December 2021, there are 17 U.S. purse seine vessels on the IATTC active purse seine register that are expected to be impacted by this action. These vessels are large, size class 6 purse seine vessels, registered to fish in the IATTC Convention Area, and primarily based in the western and central Pacific Ocean (WCPO). They are subject to the 100 percent observer coverage requirement pursuant to the AIDCP and U.S. domestic regulations at § 216.24(e)(1).

As described in the previous section, even though NMFS would exempt the regulatory requirements in § 216.24(e) to carry an observer, if there are any tuna caught on a trip in the ETP, it would be ineligible for a U.S. dolphin-safe label or an AIDCP Dolphin-Safe Tuna Certificate if no observer was on board. However, such tuna harvested in the ETP without an observer may still be legally sold in the United States, provided it was harvested in accordance with other relevant requirements.

Despite these restrictions for use of the U.S. dolphin-safe label or an AIDCP Dolphin-Safe Tuna Certificate, some U.S. purse seine vessels have made determinations that there is still a market for tuna caught without an observer. Out of the 87 trips by U.S. vessels that occurred since the observer exemptions were approved in March 2020, the United States has issued 17 observer exemptions under the authority of the NMFS Emergency Rule. Of those exemptions, approximately one third were not utilized, *i.e.,* no fishing occurred in the IATTC Convention Area during the trip for which the exemption was issued. For trips where no observer was deployed, vessels are required to submit directly to the IATTC an IATTC bridge log and a fish aggregating device (FAD) form that contains fields that would have otherwise been collected by the observer. The compliance rate with these requirements is 100 percent as of December 2021.

Lastly, beyond the aforementioned IATTC bridge log, FAD form, and NOAA Form 370 that are already collected for large purse seine trips, there are no new recordkeeping or reporting requirements associated with this action. There are also no relevant Federal rules that may duplicate, overlap, or conflict with this action.

This proposed action is not expected to substantially change the typical fishing practices of affected vessels or have a significant impact on the profitability of the affected U.S. vessels, as a relatively small number of U.S. vessels have been issued observer exemptions for trips under the NMFS Emergency Rule since March 2020. Though observer exemptions make catch of tuna in the EPO ineligible for U.S. dolphin safe label and AIDCP dolphin safe certificate, U.S. vessels and other IATTC members have found markets for catch without these labels/certificates and continue to request exemptions. The proposed action would allow U.S. large purse seine vessels to continue fishing activities in cases where it is not possible to place an observer. As such, this action is not expected to have a significant economic impact on a substantial number of small entities and will not have a disproportionate economic impact on small business entities relative to the large entities. Therefore, an Initial Regulatory Flexibility Analysis is not required and none has been prepared.

List of Subjects in 50 CFR Parts 216 and 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: January 28, 2022.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, the National Marine Fisheries Service proposes to amend 50 CFR parts 216 and 300 as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

Subpart C—General Exceptions

■ 1. The authority citation for 50 CFR part 216, subpart C, continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. Amend § 216.24(e)(1) by adding paragraphs (i) and (ii) to read as follows:

§ 216.24 Taking and related acts in commercial fishing operations including tuna purse seine vessels in the eastern tropical Pacific Ocean.

* * * * *

(e) * * *

(1) * * *

(i) *Exemption from observer requirement.* The Administrator, West Coast Region (or designee), may issue a temporary written exemption from the observer requirement in paragraph (e)(1) of this section if the Parties to the AIDCP and/or Members of the IATTC have adopted emergency observer exemption procedures to address relevant global or regional health, safety, and security concerns, as well as other international emergencies and crises. Such exemptions will be issued on a case-by-case basis for a single fishing trip, in accordance with the AIDCP/IATTC exemption procedures in effect at the time of the request. Exemptions from the requirement in paragraph (e)(1) of this section will only be issued when AIDCP/IATTC exemption procedures are in effect and are only valid for as long as the AIDCP/IATTC exemption procedures remain in effect. NMFS will notify the affected fleet via email when existing AIDCP/IATTC exemption procedures expire. NMFS will also notify the affected fleet via email and the public by publication of a notice in the **Federal Register** if new exemption procedures are adopted by the Parties to the AIDCP and/or the Members of the IATTC. Requests for exemption must be made to the Administrator, West Coast Region, via email at *WCR.HMS@noaa.gov,* or in a manner acceptable to the Administrator, West Coast Region.

(ii) [Reserved]

* * * * *

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart C—Eastern Pacific Tuna Fisheries

■ 3. The authority citation for 50 CFR part 300, subpart C, continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.*

■ 4. In § 300.24, revise paragraph (n) to read as follows:

§ 300.24 Prohibitions.

* * * * *

(n) Use a fishing vessel of class size 4–6 to fish with purse seine gear in the Convention Area in contravention of the observer requirements in § 300.25(d) or the purse seine closure period requirements in § 300.25(e)(1), (2), or (5).

* * * * *

■ 5. In § 300.25, add paragraph (d) to read as follows:

§ 300.25 Fisheries management.

* * * * *

(d) *Observer requirements.*

(1) *Purse seine vessels.*

(i) The holder of an eastern tropical Pacific Ocean vessel permit, as required by § 216.24(b) of this title, must allow an observer duly authorized by the Administrator, West Coast Region, to accompany the vessel on all fishing trips in the IATTC Convention Area for the purpose of conducting research and observing operations, including collecting information that may be used in civil or criminal penalty proceedings, forfeiture actions, or permit sanctions, pursuant to the requirements in § 216.24(e) of this title. A vessel that fails to carry an observer in accordance with these requirements may not engage in fishing operations unless an exemption has been granted from these requirements as provided for in § 216.24(e)(1)(i) of this title.

(ii) [Reserved].

(2) [Reserved].

* * * * *

[FR Doc. 2022–02162 Filed 2–3–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 20131–0037]

RIN 0648–BK79

Pacific Island Fisheries; Rebuilding Plan for the American Samoa Bottomfish Fishery

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement a rebuilding plan that includes annual catch limits (ACL) and accountability measures (AM) for the overfished bottomfish stock complex in American Samoa. This action is necessary to end overfishing and rebuild the overfished stock consistent with the requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: NMFS must receive comments by March 21, 2022.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2022–0006, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2022–0006, in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Send written comments to Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Instructions: NMFS may not consider comments sent by any other method, to any other address or individual, or received after the end of the comment period. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

The Western Pacific Fishery Management Council (Council) prepared Amendment 5 to the Fishery Ecosystem Plan for the American Samoa Archipelago (FEP), which includes a draft environmental assessment (EA) and Regulatory Impact Review. Copies of Amendment 5 and other supporting documents are available at *www.regulations.gov,* or from the Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, *www.wpcouncil.org.*

FOR FURTHER INFORMATION CONTACT: Heather Cronin, NMFS PIR Sustainable Fisheries, 808–725–5179.

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the American Samoa bottomfish fishery under the FEP and implementing regulations. The fishery primarily targets and harvests a complex of 11 bottomfish management unit species (BMUS), which includes emperors, snappers, groupers, and jacks. Bottomfish are typically harvested in deep waters, though some species are caught over reefs at shallower depths. Most (85 percent) bottomfish habitat is in territorial waters (generally from the shoreline to 3 nautical miles (5.6 km) offshore), with the rest in Federal waters (*i.e.,* the U.S Exclusive Economic Zone) around offshore banks. Fishing for bottomfish in American Samoa primarily occurs within 20 mi (32.2 km) from shore using aluminum catamarans less than 32 ft (9.7 m) long, known locally as alia.

The Council and NMFS only have the authority to develop and implement fishery management regulations in Federal waters, and the American Samoa Government has the authority to implement fishery management measures in territorial waters. Bottomfish fishermen in American Samoa are not required to obtain a Federal permit to fish for BMUS or to report their BMUS catch to NMFS. The American Samoa Department of Marine and Wildlife Resources collects fishery catch information from fishermen through voluntary creel surveys, and commercial sales data from the mandatory commercial receipt book program. There are no territorial permitting requirements to fish for bottomfish in territorial waters.

The fishery is relatively small, with fewer than 20 participants in the fishery (86 FR 3028, January 14, 2021), and primarily non-commercial, but it is still of importance to the local economy, and from social, cultural, and food security standpoints. In the past 20 years, the estimated total catch has varied from a high of 42,301 lb (19,187 kg) in 2001 to a low of 7,688 lb (3,487 kg) in 2012. The

average catch from 2018–2020 was 12,687 lb (5,755 kg), with 965 lb (438 kg) attributed to the commercial fishery and the 11,722 lb (5,317 kg) attributed to the non-commercial sector. In 2020, the commercial price was $3.48/lb ($7.67/kg) and the estimated fishery revenue was $4,018.

On February 10, 2020, NMFS notified the Council that the American Samoa bottomfish stock complex was overfished and subject to overfishing (85 FR 26940, May 6, 2020). Consistent with section 304(e) of the Magnuson-Stevens Act and implementing regulations at 50 CFR 600.310(j), the Council must prepare, and NMFS must implement, a rebuilding plan within two years of the notification. The rebuilding plan must specify the timeframe for rebuilding the stock complex's biomass to a level that is capable of producing maximum sustainable yield (B_{MSY}). The rebuilding timeframe must be as short as possible, taking into account the status and biology of the overfished stock, the needs of fishing communities, and the interaction of the overfished stock of fish within the marine ecosystem and cannot exceed 10 years, except in cases where the biology of the stock of fish, other environmental conditions, or management measures under an international agreement in which the United States participates dictate otherwise. The rebuilding must also have at least a 50 percent probability of attaining the $B_{MSY,}$ where such probabilities can be calculated.

If approved, Amendment 5 would implement a rebuilding plan for the American Samoa bottomfish stock complex that consists of an ACL and two AMs. We would set the ACL 5,000 lb (2,268 kg) starting in 2022. Because NMFS is obligated to manage the stock throughout its range, and the complex exists in both territorial and Federal waters, we would count harvests from territorial and Federal waters toward the ACL. Note, however, that existing data collection programs do not differentiate catch from territorial versus Federal waters. The fishing year is the calendar year.

As an in-season AM, if NMFS projects that the fishery will reach the ACL in any year, then we would close the fishery in Federal waters for the remainder of that year. At this time, the American Samoan Government does not have regulations in place to implement a complementary closure in territorial waters at the same time as a Federal closure. Therefore, NMFS expects there could continue to be fishing in territorial waters even after a closure of the bottomfish fishery in Federal waters, and this could offset the potential conservation benefits of restricting bottomfish harvest in Federal waters. As an additional AM, if the total annual catch (which includes catch from both Federal and territorial waters) exceeds the ACL during a year, we would close the fishery in Federal waters until NMFS and the Territory of American Samoa implement a coordinated management regime to ensure that the catch in both Federal and territorial waters is maintained at levels that allow the stock to rebuild. The rebuilding plan would remain in place until NMFS determines that the stock complex is rebuilt, which is expected to take 10 years if catches are maintained at the specified level. This rebuilding plan was selected because it allows for the least disruption to the fishing community and minimizes negative socio-economic impacts while still rebuilding the stock complex within the 10-year period required by the Magnuson-Stevens Act. NMFS and the Council would review the rebuilding plan routinely every two years and modify it, as necessary, per section 304(e)(7) of the Magnuson-Stevens Act.

NMFS must receive comments on this proposed rule by the date provided in the **DATES** section. NMFS is also soliciting comments on proposed Amendment 5; see the Notice of Availability (NOA) published on Date (FR citation). NMFS must receive comments on the NOA by Date. NMFS may not consider any comments not postmarked or otherwise transmitted by that date. NMFS will consider comments on both the NOA and this proposed rule in our decision to approve, disapprove, or partially approve Amendment 5. NMFS specifically invites public comments that address the impact of the proposed rule and Amendment 5 on cultural fishing in American Samoa.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed action is consistent with the FEP, other provisions of the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. A description of the proposed action, why it is being considered, and the legal basis for it are contained in the preamble to this proposed rule.

The American Samoa bottomfish fishery is primarily a non-commercial fishery and is relatively small, with fewer than 20 participants, many of whom also participate in other fisheries such as troll and small-scale longline. Since 2011, percent of catch sold ranged from 2.9 percent in 2011 to 15.4 percent in 2014. In 2020, fishermen sold 3.2 percent of bottomfish catch. Fishing for bottomfish primarily occurs using aluminum alia catamarans less than 32 ft (9.7 m) in length that are outfitted with outboard engines and wooden hand reels that fishermen use for both trolling and bottomfish fishing. The demand for bottomfish on American Samoa varies depending on the need for fish at community events, and alia fishermen may switch to bottomfish fishing during periods when target longline catches or prices are low. Between 2018 and 2020, the bottomfish catch averaged 12,587 lb (5,709 kg) with 7.2 percent sold, with remaining catch likely to be non-commercial catch, kept for personal consumption or shared within the community. In 2020, the most recent year for which catch data are available, the total estimated annual catch of American Samoa BMUS was 9,592 lb (4,350 kg), with commercial catch an estimated 307 lb (139 kg). Using the average bottomfish price in 2020 of $3.48/lb ($7.67/kg), 2020 bottomfish revenue is estimated to be $1,067. However, the 2020 price for bottomfish was lower than the average prices for 2017 ($5.11), 2018 ($4.25), 2019 ($4.24). Using the most recent 3-year average catch of bottomfish (12,587 lb or 5,709 kg) and the 2020 bottomfish price per pound ($3.48/lb or $7.67/kg), NMFS estimates the expected annual total revenue of the fishery to be $3,179. Under this scenario, the expected annual revenue for each of the 20 participants of this fishery from commercial bottomfish catch is $159. If NMFS were to apply a higher price to the analyses, estimated revenues and revenue losses would be higher.

Under the proposed action, with an ACL of 5,000 lb (2,269 kg) and an in-season AM to close Federal waters upon reaching the ACL for the bottomfish fishery in American Samoa, NMFS expects the fishery to exceed the ACL within the first half of the year. The reduction in catch because of this action could be offset if fishing effort in Federal waters relocates to territorial waters (assuming that the American Samoa government does not implement complementary measures in territorial waters). Without complementary

management in place, NMFS expects the fishery to land 11,534 lb (5,231 kg) or more in 2022, which would exceed the ACL. As a result, Federal waters would close. However, even after a closure of Federal waters, NMFS expects the fishery to land 10,784 lb (4,891 kg) or more from territorial waters. The expected catch would depend on the level of fishing activity transferring to territorial waters, once the in-season closure occurs. If all fishing effort that would have been conducted in Federal waters moves to territorial waters, catch could be closer to levels when the fishery had not been constrained by a limit. However, if post-closure fishing effort in Federal waters does not move to territorial waters, then implementing the proposed action would result in a potential reduction of 1,153 lb (523 kg) in catch in 2022 and 1,903 lb (863 kg) for every subsequent years of the rebuilding plan compared to the status quo. The estimated fleetwide bottomfish revenue during the first year of implementing the rebuilding plan could be as low as $2,888. Under this scenario, the 20 participants would earn approximately $144 each. For subsequent years, fleetwide revenue could be as low as $2,702 ($135 per participant). These would represent reduction in bottomfish revenue of $15 in 2022 and $24 for subsequent years, compared to the status quo. Fishermen could offset loss in revenue by selling some of their catch that had been intended to be retained or shared (non-commercial catch) or by relocating fishing effort to territorial waters which are likely to remain open.

The fishery is not expected to substantially change the way it fishes with respect to fishing gear, fishing effort, participation, or intensity, but may change slightly with respect to total catch and areas fished, with the fishermen who would normally choose to fish in Federal waters being affected more adversely. Larger impacts would occur if the American Samoa government implemented a complementary closure in territorial waters with expected fleetwide catch of 5,000 lb the first year (2,269 kg) and no bottomfish catch during subsequent years until a coordinated management approach is developed that ensures catch in both Federal and territorial waters can be maintained at levels that allow the stock to rebuild. While limiting total bottomfish catches annually may result in short-term economic impacts to fishery participants, rebuilding stock biomass to B_{MSY} is expected to increase the exploitable biomass which, in turn, is expected to provide for long-term sustainability of fishery resources while allowing fishery participants to continue to benefit from their use.

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 (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. Based on available information, NMFS has determined that all vessels subject to the proposed action are small entities, *i.e.,* they are engaged in the business of finfish harvesting (NAICS code 114111), are independently owned or operated, are not dominant in their field of operation, and have annual gross receipts not in excess of $11 million. Even though this proposed action would apply to a substantial number of vessels, the implementation of this action would not result in significant adverse economic impact to individual vessels.

The proposed action does not duplicate, overlap, or conflict with other Federal rules and is not expected to have significant impact on small entities (as discussed above), organizations or government jurisdictions. There does not appear to be disproportionate adverse economic impacts from the proposed rule based on home port, gear type, or relative vessel size. The proposed rule will not place a substantial number of small entities, or any segment of small entities, at a significant competitive disadvantage to large entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR 665

Administrative practice and procedure, American Samoa, Bottomfish, Fisheries, Fishing, Pacific Islands.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: January 31, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR part 665 as follows:

PART 665—FISHERIES IN THE WESTERN PACIFIC

■ 1. The authority citation for 50 CFR part 665 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. Revise § 665.103 to read as follows:

§ 665.103 Prohibitions.

In addition to the general prohibitions specified in § 600.725 of this chapter and § 665.15, it is unlawful for any person to do any of the following:

(a) Fish for American Samoa bottomfish MUS or ECS using gear prohibited under § 665.104.

(b) Fish for or possess any American Samoa Bottomfish MUS as defined in § 665.101 after a closure of the fishery in violation of § 665.106.

(c) Sell or offer for sale any American Samoa Bottomfish MUS as defined in § 665.101 after a closure of the fishery in violation of § 665.106.

■ 3. Add § 665.106 to read as follows:

§ 665.106 American Samoa Annual Catch Limits (ACL).

(a) In accordance with § 665.4, the ACL for American Samoa bottomfish MUS is 5,000 lb.

(b) When NMFS projects the ACL will be reached, the Regional Administrator shall publish a document to that effect in the **Federal Register** and shall use other means to notify permit holders. The document will include an advisement that the fishery will be closed, beginning at a specified date that is not earlier than seven days after the date of filing the closure notice for public inspection at the Office of the Federal Register, through the end of the fishing year in which the catch limit is reached.

(c) If the ACL is exceeded in any fishing year, the Regional Administrator shall publish a document to that effect in the **Federal Register** and shall use other means to notify permit holders. The document will include an advisement that the fishery will be closed, beginning at a specified date that is not earlier than seven days after the date of filing the closure notice for public inspection at the Office of the Federal Register. The fishery will remain closed until such time that a coordinated approach to management is developed that ensures catch in both Federal and territorial waters can be maintained at levels that allow the stock to rebuild or the rebuilding plan is modified based on the best scientific information available.

(d) On and after the date the fishery is closed as specified in paragraphs (b) or (c) of this section, fishing for and possession of American Samoa

bottomfish MUS is prohibited in the American Samoa fishery management area, except as otherwise authorized by law.

(e) On and after the date the fishery is closed as specified in paragraphs (b) or (c) of this section, the sale, offering for sale, and purchase of any American Samoa bottomfish MUS caught in the American Samoa fishery management area is prohibited.

[FR Doc. 2022–02350 Filed 2–3–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 87, No. 24
Friday, February 4, 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 Massachusetts Advisory Committee

AGENCY: 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 (FACA), that a meeting of the Massachusetts Advisory Committee to the Commission will convene by conference call on Tuesday, February 22, 2022, at 2:00 p.m. (ET). The purpose of the meeting is to discuss the next civil rights project.

DATES: Tuesday, February 22, 2022, at 2:00 p.m. (ET).

Public WEBEX Conference link (video and audio): https://tinyurl.com/2phusnmr.

To join by phone only: Dial 1–800–360–9505; Access code: 2763 253 8781#.

FOR FURTHER INFORMATION CONTACT: Evelyn Bohor at *ero@usccr.gov* or by phone at 202–921–2212.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the WebEx link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and 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 call-in number found through registering at the web link provided above for the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the respective meeting. Written comments may be emailed to Ivy Davis at *ero@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 809–9618. Records and documents discussed during the meeting will be available for public viewing as they become available at the *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda

Tuesday, February 22, 2022; 2:00 p.m. (ET)

1. Roll call
2. Concept Gate and Next Steps
3. Public Comment
4. Other Business
5. Adjourn

Dated: February 1, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–02384 Filed 2–3–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–887]

Carbon and Alloy Steel Cut-to-Length Plate From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on carbon and alloy steel cut-to-length plate from the Republic of Korea. The period of review (POR) is May 1, 2019, through April 30, 2020. The review covers one producer/exporter of the subject merchandise, POSCO and its affiliated companies (collectively, the POSCO single entity). We determine that sales of subject merchandise by the POSCO single entity were not made at prices below normal value (NV).

DATES: Applicable February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Janae Martin or William Horn, 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) 482–0608 or (202) 482–4868, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* on August 6, 2021.[1] We invited interested parties to comment on the *Preliminary Results.* For a complete description of the events that occurred subsequent to the *Preliminary Results, see* the Issues and Decision Memorandum.[2]

Scope of the Order [3]

The merchandise subject to the *Order* is carbon and alloy steel cut-to-length plate. The product is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7225.40.1110, 7225.40.1180, 7225.40.3005, 7225.40.3050, 7226.20.0000, and 7226.91.5000.

The products subject to the *Order* may also enter under the following HTSUS subheadings: 7208.40.6060, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.19.1500, 7211.19.2000, 7211.19.4500, 7211.19.6000, 7211.19.7590, 7211.90.0000, 7212.40.1000, 7212.40.5000,

[1] *See Carbon and Alloy Steel Cut-to-Length Plate from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020;* 86 FR 43178 (August 6, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results in the 2019–2020 Antidumping Duty Administrative Review of Carbon and Alloy Steel Cut-to-Length Plate from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See Certain Carbon and Alloy Steel Cut-To-Length Plate from Austria, Belgium, France, the Federal Republic of Germany, Italy, Japan, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Determinations for France, the Federal Republic of Germany, the Republic of Korea and Taiwan, and Antidumping Duty Orders,* 82 FR 24096 (May 25, 2017) (*Order*).

7212.50.0000, 7214.10.000, 7214.30.0010, 7214.30.0080, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7225.11.0000, 7225.19.0000, 7225.40.5110, 7225.40.5130, 7225.40.5160, 7225.40.7000, 7225.99.0010, 7225.99.0090, 7206.11.1000, 7226.11.9060, 7229.19.1000, 7226.19.9000, 7226.91.0500, 7226.91.1530, 7226.91.1560, 7226.91.2530, 7226.91.2560, 7226.91.7000, 7226.91.8000, and 7226.99.0180.

The HTSUS subheadings are provided for convenience and customs purposes only; the written product description of the scope of the *Order* is dispositive. For a complete description of the scope of the *Order, see* the accompanying Issues and Decisions Memorandum.[4]

Analysis of Comments Received

All issues raised in the parties' case and rebuttal briefs are addressed in the Issues and Decision Memorandum and are listed in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on-file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on the comments received from interested parties and record information, we made no changes to our preliminary margin calculations for the POSCO single entity.

Final Results of the Review

As a result of this review, we determine the following weighted-average dumping margin exists for the POR:

Exporter or producer	Weighted-average dumping margin (percent)
POSCO single entity[5]	00.00

Disclosure

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with a final results of review, in accordance with 19 CFR 351.224(b). However, because Commerce made no adjustments to the margin calculation methodology used in the *Preliminary Results,* there are no additional calculations to disclose for the final results of this review.

Assessment Rates

Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with these final results of review.[6] Because the weighted-average dumping margin for the POSCO single entity is zero percent, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[7]

Commerce's ''reseller policy'' will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[8]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the POSCO single entity will be equal to the weighted-average dumping margin established in the final results of this administrative review (*i.e.,* zero percent); (2) for merchandise exported by a producer or exporter not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the producer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers and exporters will continue to be 7.10 percent *ad valorem,* the all-others rate established in the LTFV investigation.[9]

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance

[4] *See* Issues and Decisions Memorandum at 2–7.

[5] Commerce continues to determine that POSCO, POSCO International Corporation, POSCO SPS, and certain distributors and service centers (Taechang Steel Co., Ltd., Winsteel Co., Ltd., and Shinjin Esco Co., Ltd.) are affiliated pursuant to section 771(33)(E) of the Tariff Act of 1930, as amended (the Act), and that these companies should be treated as a single entity (collectively, the POSCO single entity) pursuant to 19 CFR 351.401(f). Our collapsing determination with respect to Shinjin Esco Co., Ltd. relates only to the portion of the POR during which the company was affiliated with POSCO, *i.e.,* from May 1, 2019, to February 10, 2020. *See Preliminary Results; see also* Memorandum, ''2019–2020 Antidumping Duty Administrative Review of Certain Carbon and Alloy Steel Cut-to-Length Plate from the Republic of Korea: Affiliation and Collapsing Memorandum,'' dated July 30, 2021.

[6] *See* 19 CFR 351.212(b).

[7] *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).

[8] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[9] *See Order,* 82 FR 24098.

with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: January 28, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. The POSCO Single Entity
V. Discussion of the Issues
Comment 1: Collapsing Taechang and Winsteel with POSCO
VI. Recommendation

[FR Doc. 2022–02308 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–834]

Certain Carbon and Alloy Steel Cut-To-Length Plate From Italy: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that producers and/or exporters subject to this administrative review made sales of subject merchandise at less than normal value during the period of review (POR), May 1, 2019, through April 30, 2020. Additionally, Commerce determines that a company for which we initiated a review had no shipments during the POR.

DATES: Applicable February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Alice Maldonado or David Crespo, 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) 482–4682 or (202) 482–3693, respectively.

SUPPLEMENTARY INFORMATION:

Background

This review covers ten producers and/or exporters of the subject merchandise. Commerce selected two companies, NLMK Verona SpA (NVR) and Officine Tecnosider s.r.l. (OTS), for individual examination. The producers and/or exporters not selected for individual examination are listed in the ''Final Results of the Review'' section of this notice.

On August 4, 2021, Commerce published the *Preliminary Results*.[1] In September 2021, certain of the petitioners [2] and NVR submitted case and rebuttal briefs. On November 30, 2021, we extended the deadline for the final results by 57 days, until January 28, 2022.[3] For a description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[4]

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the order are certain carbon and alloy steel hot-rolled or forged flat plate products not in coils, whether or not painted, varnished, or coated with plastics or other non-metallic substances from Italy. Products subject to the order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7225.40.1110, 7225.40.1180, 7225.40.3005, 7225.40.3050, 7226.20.0000, and 7226.91.5000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.[5]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are listed in the appendix to this notice and addressed in the Issues and Decision Memorandum. 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 directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Determination of No Shipments

As noted in the *Preliminary Results,* we received a no-shipment claim from one company involved in this administrative review, Lyman Steel Company (Lyman). In the *Preliminary Results,* we preliminarily determined that Lyman had no reviewable transactions during the POR. We received no comments from interested parties with respect to this claim. Therefore, because the record indicates that this company did not export subject merchandise to the United States during the POR, we continue to find that Lyman had no reviewable transactions during the POR. Accordingly, consistent with Commerce's practice, we intend to instruct U.S. Customs and Border Protection (CBP) to liquidate any existing entries of merchandise produced by Lyman, but exported by other parties, at the rate for the intermediate reseller, if available, or at the all-others rate.[6]

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* we made changes to the preliminary weighted-average margin calculations for OTS, NVR, and those companies not selected for individual review.[7]

Rate for Non-Selected Respondents

The Act and Commerce's regulations do not address the establishment of a

[1] *See Certain Carbon and Alloy Steel Cut-To-Length Plate from Italy: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020,* 86 FR 41953 (August 4, 2021) (*Preliminary Results*).

[2] Nucor Corporation.

[3] *See* Memorandum, ''Extension of Deadline for Final Results of 2019–2020 Antidumping Duty Administrative Review,'' dated November 30, 2021.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2019–2020 Administrative Review of the Antidumping Duty Order on Certain Carbon and Alloy Steel Cut-To-Length Plate from Italy,'' dated concurrently with, and hereby adopted by, these results (Issues and Decision Memorandum).

[5] For a full description of the scope of the order, *see* Issues and Decision Memorandum.

[6] *See, e.g., Magnesium Metal from the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 26922, 26923 (May 13, 2010), unchanged in *Magnesium Metal from the Russian Federation: Final Results of Antidumping Duty Administrative Review,* 75 FR 56989 (September 17, 2010).

[7] *See* Issues and Decision Memorandum.

rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this review, we have calculated a weighted-average dumping margin for the non-selected companies by using the weighted-average calculated rates of the mandatory respondents, NVR and OTS, which are not zero, *de minimis,* or determined entirely on the basis of facts available.[8] For these final results, we have calculated a weighted-average dumping margin for OTS that is zero. Accordingly, we have assigned to the companies not individually examined the weighted-average dumping margin calculated for NVR.

Final Results of the Review

We are assigning the following weighted-average dumping margins to the firms listed below for the period May 1, 2019, through April 30, 2020:

Exporters/producers	Weighted-average dumping margin (percent)
NLMK Verona SpA	1.57
Officine Tecnosider s.r.l	0.00
Rate Applicable to the Following Non-Selected Companies:	
Arvedi Tubi Acciaio	1.57
C.M.T. Construzioni Meccaniche di Taglione Emilio & C. S.a.s	1.57
MAM s.r.1	1.57
O.ME.P SpA	1.57
Ofar SpA	1.57
Sesa SpA	1.57
Tim-Cop Doo Temerin	1.57

Disclosure

Commerce intends to disclose the calculations performed in connection with these final results of review to parties in this review within five days after public announcement of the final results or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Where the respondent did not report entered value or reported amounts based on estimated data, we calculated the entered value in order to calculate the assessment rate. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the companies that were not selected for individual review, we will assign an assessment rate based on the cash deposit rate calculated for NVR.[9] The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[10]

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. As indicated above, for Lyman, we will instruct CBP to liquidate any existing entries of merchandise produced by Lyman, but exported by other parties, at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective 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 each specific company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not participating in this review, the cash deposit will continue to be the

[8] *See* section 735(c)(5)(A) of the Act.

[9] This rate was calculated as discussed in the Section, ''Rate for Non-Selected Respondents,'' above.

[10] *See* section 751(a)(2)(C) of the Act.

company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 6.08 percent, the all-others rate established in the LTFV investigation.[11] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

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

This notice is being issued in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

[11] *See Certain Carbon and Alloy Steel Cut-To-Length Plate from Austria, Belgium, France, the Federal Republic of Germany, Italy, Japan, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Determinations for France, the Federal Republic of Germany, the Republic of Korea, and Taiwan, and Antidumping Duty Orders,* 82 FR 24096, 24098 (May 25, 2017).

Dated: January 28, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Margin Calculations
V. Discussion of the Issues
Comment 1: NVR's Major Input Rule
Comment 2: Whether Commerce Should Adjust NVR's Total Cost of Manufacturing (TOTCOM) Calculation for Unsupported Adjustments in Its Overall Reconciliation
Comment 3: NVR's General and Administrative (G&A) Expense Calculation
Comment 4: NVR's Interest Income Calculation
Comment 5: Whether Section 232 Duties Should be Deducted From U.S. Price
Comment 6: Section 232 Duties Calculation for NVR
VI. Recommendation

[FR Doc. 2022–02280 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping duty (AD) and countervailing duty (CVD) orders with December anniversary dates. In accordance with Commerce's regulations, we are initiating those administrative reviews.

DATES: Applicable February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, 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) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

Commerce has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various AD and CVD orders and findings with December anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify Commerce within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *https://access.trade.gov,* in accordance with 19 CFR 351.303.[1] Such submissions are subject to verification, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on Commerce's service list.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the POR. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted within seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments within five days after the deadline for the initial comments.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act, the following guidelines regarding collapsing of companies for purposes of respondent selection will apply. In general, Commerce has found that determinations concerning whether particular companies should be ''collapsed'' (*e.g.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often

[1] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this AD proceeding (*e.g.,* investigation, administrative review, new shipper review, or changed circumstances review). For any company subject to this review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (Q&V) Questionnaire for purposes of respondent selection, in general, each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where Commerce considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of a particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[2] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial responses to section D of the questionnaire.

Separate Rates

In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is Commerce's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, Commerce analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, Commerce assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, Commerce requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on Commerce's website at *https://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [3] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[4] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Application will be available on Commerce's website at *https://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Application, refer to the instructions contained in the application. Separate Rate Applications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate

[2] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[3] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

[4] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

Exporters and producers must file a timely Separate Rate Application or Certification if they want to be considered for respondent selection. Furthermore, exporters and producers who submit a Separate Rate Application or Certification and subsequently are selected as mandatory respondents will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following AD and CVD orders and findings. We intend to issue the final results of these reviews not later than December 31, 2022.

	Period to be reviewed
AD Proceedings	
INDIA: Forged Steel Fittings, A–533–891	5/28/20–11/30/21
Shakti Forge Industries Pvt. Ltd.[5]	
OMAN: Circular Welded Carbon-Quality Steel Pipe, A–523–812	12/1/20–11/30/21
Al Jazeera Steel Products Co. SAOG[6]	
Al Samna Metal Manufacturing & Trading Company LLC	
Bollore Logistics (Oman) LLC	
Transworld Shipping Trading & Logistics Services LLC	
REPUBLIC OF KOREA: Welded Line Pipe, A–580–876	12/1/20–11/30/21
AJU BESTEEL Co., Ltd.	
BDP International, Inc.	
Daewoo International Corporation	
Dongbu Incheon Steel Co.	
Dongbu Steel Co., Ltd.	
Dongkuk Steel Mill	
Dong Yang Steel Pipe	
EEW Korea Co., Ltd.	
HISTEEL Co., Ltd.	
Husteel Co., Ltd.	
Hyundai RB Co. Ltd.	
Hyundai Steel Company/Hyundai HYSCO	
Kelly Pipe Co., LLC	
Keonwoo Metals Co., Ltd.	
Kolon Global Corp.	
Korea Cast Iron Pipe Ind. Co., Ltd.	
Kurvers Piping Italy S.R.L.	
MSTEEL Co., Ltd.	
Miju Steel MFG Co., Ltd.	
NEXTEEL Co., Ltd.	
Poongsan Valinox (Valtimet Division)	
POSCO	
POSCO Daewoo	
R&R Trading Co. Ltd.	
Sam Kang M&T Co., Ltd.	
SeAH Steel Corporation	
Sin Sung Metal Co., Ltd.	
SK Networks	
Soon-Hong Trading Company	
Steel Flower Co., Ltd.	
TGS Pipe	
Tokyo Engineering Korea Ltd.	
REPUBLIC OF KOREA: Forged Steel Fittings, A–580–904	05/28/20–11/30/21
Samyoung Fitting Co., Ltd.	
TAIWAN: Narrow Woven Ribbons with Woven Selvedge,[7] A–583–844	09/01/20–08/31/21
THE PEOPLE'S REPUBLIC OF CHINA: Cased Pencils, A–570–827	12/1/20–11/30/21
Ningbo Homey Union Co., Ltd.	
Shandong Wah Yuen Stationery Co. Ltd.	
Tianjin Tonghe Stationery Co. Ltd.	
Wah Yuen Stationery Co. Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Crystalline Silicon Photovoltaic Cells, Whether Or Not Assembled Into Modules, A–570–979	12/1/20—11/30/21
Amass Freight International Co Ltd	
Anji Dasol Solar Energy Science & Technology Co., Ltd.	
Boe Technology (HK) Limited	
BYD (Shangluo) Industrial Co., Ltd.	
BYD H.K. Co., Ltd.	
Canadian Solar International Limited; Canadian Solar Manufacturing (Changshu) Inc.; Canadian Solar Manufacturing (Luoyang) Inc.; CSI Cells Co., Ltd.; CSI Solar Power (China) Inc.; CSI–GCL Solar Manufacturing (Yancheng) Co., Ltd.	
Chint Energy (Haining) Co., Ltd.; Chint Solar (Hong Kong) Company Limited; Chint Solar (Jiuquan) Co., Ltd.; Chint Solar (Zhejiang) Co., Ltd.; Chint New Energy Technology (Haining) Co. Ltd.	
CSI Modules (Dafeng) Co. Ltd.	
De-Tech Trading Limited HK	

	Period to be reviewed
Dongguan Sunworth Solar Energy Co. Ltd.	
Fuzhou Sunmodo New Energy Equipment	
Hengdian Group DMEGC Magnetics Co. Ltd.	
JA Solar Co., Ltd.	
JA Solar Technology Yangzhou Co., Ltd.	
Jiangsu Crevo Science & Technology	
Jiangsu High Hope International	
Jinko Solar Import and Export Co., Ltd; Jinko Solar Co., Ltd.; JinkoSolar Technology (Haining) Co., Ltd.; Yuhuan Jinko Solar Co., Ltd.; Zhejiang Jinko Solar Co., Ltd.; Jiangsu Jinko Tiansheng Solar Co., Ltd.	
Jiawei Solarchina (Shenzhen) Co., Ltd.	
Jiawei Solarchina Co., Ltd.	
JingAo Solar Co., Ltd.	
Jinko Solar International Limited	
Lightway Green New Energy Co., Ltd.	
Longi (HK) Trading Ltd.	
LONGi Solar Technology Co., Ltd.	
Ningbo ETDZ Holdings, Ltd.	
Ningbo Qixin Solar Electrical Appliance Co., Ltd.	
Penglai Jutal Offshore Engineering	
Qinhuangdao Boostsolar Photovoltaic	
Renesola Jiangsu Ltd.	
ReneSola Zhejiang Ltd.	
Risen Energy Co. Ltd.; Risen Energy (Changzhou) Co., Ltd.; Risen (Wuhai) New Energy Co., Ltd.; Zhejiang Twinsel Electronic Technology Co., Ltd.; Risen (Luoyang) New Energy Co., Ltd.; Jiujiang Shengchao Xinye Technology Co., Ltd.; Jiujiang Shengzhao Xinye Trade Co., Ltd.; Ruichang Branch, Risen Energy (HongKong) Co., Ltd.	
Shanghai BYD Co., Ltd.	
Shanghai JA Solar Technology Co., Ltd., Shanghai Sansi Electronic	
Shanxi Hando Xinyu Technology Co Ltd	
Shenzhen Glory Industries Co., Ltd.	
Shenzhen Sungold Solar Co., Ltd.	
Shenzhen Topray Solar Co., Ltd.	
''Shenzhen Yingli New Energy Resources Co., Ltd.; Baoding Jiasheng Photovoltaic Technology Co., Ltd.; Baoding Tianwei Yingli New Energy Resources Co., Ltd.; Beijing Tianneng Yingli New Energy Resources Co., Ltd.; Hainan Yingli New Energy Resources Co., Ltd.; Hengshui Yingli New Energy Resources Co., Ltd.; Lixian Yingli New Energy Resources Co., Ltd.; Tianjin Yingli New Energy Resources Co., Ltd.; Yingli Energy (China) Company Limited.''	
Sumec Hardware & Tools Co., Ltd.; A respondent in AR8, but not granted in AR8 prelim	
Sunpower Corporation, System	
Suntech Power Co., Ltd.	
Taizhou BD Trade Co., Ltd.	
tenKsolar (Shanghai) Co., Ltd	
Trina Solar Co., Ltd.; Trina Solar (Changzhou) Science and Technology Co., Ltd.; Yancheng Trina Guoneng Photovoltaic Technology Co., Ltd.; Changzhou Trina Solar Yabang Energy Co., Ltd.; Turpan Trina Solar Energy Co., Ltd.; Hubei Trina Solar Energy Co., Ltd.; Trina Solar (Hefei) Science and Technology Co., Ltd.; Changzhou Trina Hezhong Photoelectric Co., Ltd.	
Trina Solar (Singapore) Science and Technology Pte. Ltd.	
Trina Solar Energy Development Company Limited	
Trina Solar Science & Technology (Thailand) Ltd.	
Wuxi Suntech Power Co., Ltd.; Luoyang Suntech Power Co., Ltd.	
Wuxi Tianran Photovoltaic Co., Ltd.	
Xiamen Yiyusheng Solar Co., Ltd.	
Yingli Green Energy International Trading Company Limited	
Zhejiang Aiko Solar Energy Technology Co., Ltd.	
Zhejiang Garden Imp&Exp Co., Ltd	
THE PEOPLE'S REPUBLIC OF CHINA: Diamond Sawblades and Parts Thereof, A–570–900	11/1/20–10/31/21
The China-Wide Entity [8]	
THE PEOPLE'S REPUBLIC OF CHINA: Multilayered Wood Flooring, A–570–970	12/1/20–11/30/21
Anhui Longhua Bamboo Product Co., Ltd.	
Arte Mundi Group Co., Ltd.[9]	
Arte Mundi (Shanghai) Aesthetic Home Furnishings Co., Ltd. (successor-in-interest to Scholar Home (Shanghai) New Material Co., Ltd.)	
A-Timber Flooring Company Limited	
Benxi Flooring Factory (General Partnership)	
Benxi Wood Company	
Dalian Deerfu Wooden Product Co., Ltd.	
Dalian Jiahong Wood Industry Co., Ltd.	
Dalian Penghong Floor Products Co., Ltd./Dalian Shumaike Floor Manufacturing Co., Ltd.	
Dalian Shengyu Science and Technology Development Co., Ltd.	
Dongtai Fuan Universal Dynamics, LLC	
Dun Hua Sen Tai Wood Co., Ltd.	
Dunhua City Dexin Wood Industry Co., Ltd.	
Dunhua City Hongyuan Wood Industry Co., Ltd.	
Dunhua Shengda Wood Industry Co., Ltd.	
HaiLin LinJing Wooden Products Co., Ltd.	

	Period to be reviewed
Hunchun Xingjia Wooden Flooring Inc.	
Huzhou Chenghang Wood Co., Ltd.	
Huzhou Fulinmen Imp. & Exp. Co., Ltd.	
Huzhou Sunergy World Trade Co., Ltd.	
Jiangsu Guyu International Trading Co., Ltd.	
Jiangsu Keri Wood Co., Ltd.	
Jiangsu Mingle Flooring Co., Ltd.	
Jiangsu Senmao Bamboo and Wood Industry Co., Ltd.	
Jiangsu Simba Flooring Co., Ltd.	
Jiangsu Yuhui International Trade Co., Ltd.	
Jiashan HuiJiaLe Decoration Material Co., Ltd.	
Jiashan On-Line Lumber Co., Ltd.	
Jiaxing Hengtong Wood Co., Ltd.	
Kingman Floors Co., Ltd.	
Kingman Wood Industry Co., Ltd.	
Lauzon Distinctive Hardwood Flooring, Inc.	
Linyi Anying Wood Co., Ltd.	
Linyi Youyou Wood Co., Ltd.	
Metropolitan Hardwood Floors, Inc.	
Muchsee Wood (Chuzhou) Co., Ltd.	
Pinge Timber Manufacturing (Zhejiang) Co., Ltd.	
Power Dekor Group Co., Ltd.	
Sino-Maple (Jiangsu) Co., Ltd.	
Suzhou Dongda Wood Co., Ltd.	
Tongxiang Jisheng Import and Export Co., Ltd.	
Yekalon Industry Inc.	
Yihua Lifestyle Technology Co., Ltd. (successor-in-interest to Guangdong Yihua Timber Industry Co., Ltd.)	
Yingyi-Nature (Kunshan) Wood Industry Co., Ltd.	
Zhejiang Dadongwu Greenhome Wood Co., Ltd.[10]	
Zhejiang Fuerjia Wooden Co., Ltd	
Zhejiang Longsen Lumbering Co., Ltd.	
Zhejiang Shiyou Timber Co., Ltd.	
Zhejiang Shuimojiangnan New Material Technology Co., Ltd.	
Zhejiang Yuhua Timber Co. Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Refillable Stainless Steel Kegs, A–570–093	12/1/20–11/30/21
Equipmentimes (Dalian) E-Commerce Co., Ltd.	
Guangzhou Jingye Machinery Co., Ltd.	
Guangzhou Ulix Industrial & Trading Co., Ltd	
Jinan HaoLu Machinery Equipment Co., Ltd.	
Jinjiang Jiaxing Import and Export Co., Ltd.	
NDL Keg Qingdao Inc.	
Ningbo All In Brew Technology Co.	
Ningbo BestFriends Beverage Containers Industry Co., Ltd.	
Ningbo Chance International Trade Co., Ltd.	
Ningbo Direct Import & Export Co., Ltd.	
Ningbo Haishu Direct Import and Export Trade Co., Ltd	
Ningbo Haishu Xiangsheng Metal Factory	
Ningbo Hefeng Container Manufacture Co., Ltd.	
Ningbo Hefeng Kitchen Utensils Manufacture Co., Ltd.	
Ningbo HGM Food Machinery Co., Ltd.	
Ningbo Jiangbei Bei Fu Industry and Trade Co., Ltd.	
Ningbo Kegco International Trade Co., Ltd.	
Ningbo Kegstorm Stainless Steel Co., Ltd.	
Ningbo Minke Import & Export Co., Ltd.	
Ningbo Sanfino Import & Export Co., Ltd.	
Ningbo Shimaotong International Co., Ltd.	
Ningbo Sunburst International Trading Co., Ltd.	
Orient Equipment (Taizhou) Co., Ltd.	
Penglai Jinfu Stainless Steel Products Co., Ltd.	
Pera Industry Shanghai Co., Ltd.	
Qingdao Henka Precision Technology Co., Ltd.	
Qingdao Xinhe Precision Manufacturing Co., Ltd	
Rain Star International Trading Dalian Co., Ltd.	
Shandong Tiantai Beer Equipment Co., Ltd.	
Shandong Tonsen Equipment Co., Ltd.	
Shandong Yuesheng Beer Equipment Co., Ltd.	
Shenzhen Wellbom Technology Co., Ltd	
Sino Dragon Group, Ltd.	
Wenzhou Deli Machinery Equipment Co.	
Wuxi Taihu Lamps and Lanterns Co., Ltd	
Yantai Toptech Ltd	
Yantai Trano New Material Co., Ltd.	
TURKEY: Welded Line Pipe, A–489–822	12/1/20–11/30/21
Borusan Istikbal Ticaret	

	Period to be reviewed
Borusan Mannesmann Boru Sanayi ve Ticaret A.	
Cayirova Boru Sanayii ve Ticaret A.S.	
Cimtas Boru Imalatlari ve Ticaret, Ltd. Sti	
Emek Boru Makina Sanayi ve Ticaret A.S.	
Erbosan Erciyas Tube Industry and Trade Co. Inc.	
Erciyas Celik Boru Sanayii A.S.	
Guven Celik Boru Sanayii ve Ticaret Ltd. Sti.	
Has Altinyagmur celik Boru Sanayii ve Ticaret Ltd. Sti.	
HDM Steel Pipe Industry & Trade Co. Ltd.	
Metalteks Celik Urunleri Sanayii	
MMZ Onur Boru Profil Uretim Sanayii ve Ticaret A.S.	
Noksel Steel Pipe Co. Inc.	
Ozbal Celik Boru	
Toscelik Profile and Sheet Industry, Co.	
Tosyali Dis Ticaret A.S.	
Umran Celik Boru Sanayii	
YMS Pipe & Metal Sanayii A.S.	
Yucelboru Ihracat Ithalat Pazzarlam	
UNITED ARAB EMIRATES: Circular Welded Carbon-Quality Steel Pipe, A–520–807	12/1/20–11/30/21
Ajmal Steel Tubes and Pipes Industries, LLC	
Conares Metal Supply Limited	
K.D. Industries Inc.	
Tiger Steel Industries LLC	
TSI Metal Industries L.L.C	
Universal Tube and Plastic Industries, Ltd.; KHK Scaffolding and Formwork LLC; and THL Pipe and Tube Industries LLC	
CVD Proceedings	
THE PEOPLE'S REPUBLIC OF CHINA: Crystalline Silicon Photovoltaic Cells, Whether Or Not Assembled Into Modules, C–570–980	1/1/20–12/31/20
Anji Dasol Solar Energy Science & Technology Co., Ltd.	
Astronergy Co., Ltd.	
Astronergy Solar	
Baoding Jiasheng Photovoltaic Technology Co., Ltd.	
Baoding Tianwei Yingli New Energy Resources Co., Ltd.	
Beijing Tianneng Yingli New Energy Resources Co., Ltd.	
Boviet Solar Technology Co., Ltd.	
BYD (Shangluo) Industrial Co., Ltd.	
BYD (Shaoguan) Co., Ltd.	
Canadian Solar (USA) Inc.	
Canadian Solar Inc.	
Canadian Solar International Limited	
Canadian Solar Manufacturing	
Canadian Solar Manufacturing (Changshu), Inc.	
Canadian Solar Manufacturing (Luoyang) Inc.	
Changzhou Trina Hezhong Photoelectric Co., Ltd.	
Changzhou Trina Solar Energy Co., Ltd	
Changzhou Trina Solar Yabang Energy Co., Ltd.	
Chint New Energy Technology (Haining) Co., Ltd.	
Chint Solar (HongKong) Company Limited	
Chint Solar (Jiuquan) Co., Ltd.	
Chint Solar (Zhejiang) Co., Ltd.	
CSI Cells Co., Ltd.	
CSI Modules (Dafeng) Co., Ltd.	
CSI Solar Power (China) Inc.	
CSI–GCL Solar Manufacturing (Yancheng) Co., Ltd.	
DelSolar (Wujiang) Ltd.	
DelSolar Co., Ltd.	
De-Tech Trading Limited HK	
Dongguan Sunworth Solar Energy Co., Ltd.	
Eoplly New Energy Technology Co., Ltd.	
ERA Solar Co., Ltd.	
ET Solar Energy Limited	
Fuzhou Sunmodo New Energy Equipment Co., Ltd.	
GCL System Integration Technology Co. Ltd.	
Hainan Yingli New Energy Resources Co., Ltd.	
Hangzhou Sunny Energy Science and Technology Co., Ltd.	
Hefei JA Solar Technology Co., Ltd.	
Hengdian Group DMEGC Magnetics Co., Ltd.	
Hengshui Yingli New Energy Resources Co., Ltd.	
Hubei Trina Solar Energy Co., Ltd.	
JA Solar (Xingtai) Co., Ltd.	
JA Solar Co., Ltd. (aka JingAo Solar Co., Ltd.)	
JA Solar International Limited	

	Period to be reviewed
JA Solar Technology Yangzhou, Co., Ltd.	
Jiangsu High Hope Int'l Group	
Jiangsu Huayou International Logistics	
Jiangsu Jinko Tiansheng Solar Co., Ltd.	
Jinko Solar Co., Ltd.	
Jinko Solar Import and Export Co., Ltd.	
Jinko Solar International Limited	
Jinko Solar Technology (Haining) Co., Ltd.	
Jiujiang Shengchao Xinye Trade Co., Ltd., Ruichang Branch	
Jiujiang Shengzhao Xinye Technology Co., Ltd.	
Light Way Green New Energy Co., Ltd.	
Lixian Yingli New Energy Resources Co., Ltd.	
Longi (HK) Trading Ltd.	
LONGi Solar Technology Co, Ltd.	
Luoyang Suntech Power Co., Ltd.	
Nice Sun PV Co., Ltd.	
Ningbo ETDZ Holdings Ltd.	
Penglai Jutal Offshore Engineering	
ReneSola Jiangsu Ltd.	
Renesola Zhejiang Ltd.	
Risen (Luoyang) New Energy Co., Ltd.	
Risen (Wuhai) New Energy Co., Ltd.	
Risen Energy (Changzhou) Co., Ltd.	
Risen Energy (Yiwu) Co., Ltd.	
Risen Energy Co., Ltd.	
Risen Energy (HongKong) Co., Ltd.	
Shanghai BYD Co., Ltd.	
Shanghai JA Solar Technology Co., Ltd.	
Shenzhen Sungold Solar Co., Ltd.	
Shenzhen Topray Solar Co., Ltd.	
Shenzhen Yingli New Energy Resources Co., Ltd.	
Solar Philippines Module	
Sumec Hardware and Tools Co., Ltd.	
Sunpreme Solar Technology (Jiaxing) Co., Ltd.	
Suntech Power Co., Ltd.	
Suntimes Technology Co., Limited	
Systemes Versilis, Inc.	
Taimax Technologies Inc.	
Taizhou BD Trade Co., Ltd.	
Talesun Energy	
Talesun Solar	
tenKsolar (Shanghai) Co., Ltd.	
Tianjin Yingli New Energy Resources Co., Ltd.	
Toenergy Technology Hangzhou Co., Ltd	
Trina (Hefei) Science and Technology Co., Ltd.	
Trina Solar (Changzhou) Science and Technology Co. Ltd.	
Trina Solar Co., Ltd.	
Turpan Trina Solar Energy Co., Ltd.	
Vina Solar Technology Co., Ltd.	
Wuxi Suntech Power Co., Ltd.	
Wuxi Tianran Photovoltaic Co., Ltd.	
Yancheng Trina Solar Energy Technology Co., Ltd.	
Yancheng Trinasolar Guoneng Science	
Yingli Energy (China) Co., Ltd.	
Yingli Green Energy International Trading Company Limited	
Yuhuan Jinko Solar Co., Ltd.	
Zhejiang ERA Solar Technology Co., Ltd.	
Zhejiang Jinko Solar Co., Ltd.	
Zhejiang Sunflower Light Energy Science & Technology Limited Liability	
Zhejiang Twinsel Electronic Technology Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Multilayered Wood Flooring, C–570–971	1/1/20–12/31/20
A-Timber Flooring Company Limited	
Anhui Boya Bamboo & Wood Products Co., Ltd.	
Anhui Longhua Bamboo Product Co., Ltd.	
Anhui Yaolong Bamboo & Wood Products Co. Ltd.	
Armstrong Wood Products (Kunshan) Co., Ltd.	
Arte Mundi Group Co., Ltd. (f.k.a., Arte Mundi (Shanghai) Aesthetic Home Furnishings Co., Ltd., and Scholar Home (Shanghai) New Material Co., Ltd.)	
Baroque Timber Industries (Zhongshan) Co., Ltd	
Benxi Flooring Factory (General Partnership)	
Benxi Wood Company	
Changzhou Hawd Flooring Co., Ltd.	
Dalian Guhua Wooden Product Co., Ltd.	
Dalian Huilong Wooden Products Co., Ltd.	

	Period to be reviewed
Dalian Jaenmaken Wood Industry Co., Ltd.	
Dalian Jiahong Wood Industry Co., Ltd.	
Dalian Kemian Wood Industry Co., Ltd.	
Dalian Penghong Floor Products Co., Ltd.	
Dalian Qianqiu Wooden Product Co., Ltd.	
Dalian Shengyu Science And Technology Development Co., Ltd.	
Dalian Shumaike Floor Manufacturing Co., Ltd.	
Dalian T-Boom Wood Products Co., Ltd.	
Dongtai Fuan Universal Dynamics, LLC	
Dunhua City Dexin Wood Industry Co., Ltd.	
Dunhua City Hongyuan Wood Industry Co., Ltd.	
Dunhua City Jisen Wood Industry Co., Ltd.	
Dun Hua Sen Tai Wood Co., Ltd.	
Dunhua Shengda Wood Industry Co., Ltd.	
Fine Furniture (Shanghai) Limited	
Fusong Jinlong Wooden Group Co., Ltd.	
Fusong Jinqiu Wooden Product Co., Ltd.	
Fusong Qianqiu Wooden Product Co., Ltd.	
Guangdong Yihua Timber Industry Co., Ltd	
Guangzhou Homebon Timber Manufacturing Co., Ltd.	
HaiLin LinJing Wooden Products, Ltd.	
Hangzhou Hanje Tec Company Limited	
Hangzhou Zhengtian Industrial Co., Ltd.	
Hong Kong Chuanshi International	
Hunchun Forest Wolf Wooden Industry Co., Ltd.	
Hunchun Xingjia Wooden Flooring Inc.	
Huzhou Chenghang Wood Co., Ltd.	
Huzhou Fulinmen Imp. & Exp. Co., Ltd.	
Huzhou Jesonwood Co., Ltd	
Huzhou Sunergy World Trade Co., Ltd	
Jiangsu Guyu International Trading Co., Ltd.	
Jiangsu Keri Wood Co., Ltd.	
Jiangsu Mingle Flooring Co., Ltd.	
Jiangsu Senmao Bamboo and Wood Industry Co., Ltd.	
Jiangsu Simba Flooring Co., Ltd	
Jiangsu Yuhui International Trade Co., Ltd.	
Jiashan HuiJiaLe Decoration Material Co., Ltd.	
Jiashan On-Line Lumber Co., Ltd.	
Jiaxing Brilliant Import & Export Co., Ltd.	
Jiaxing Hengtong Wood Co., Ltd.	
Jilin Xinyuan Wooden Industry Co., Ltd.	
Karly Wood Product Limited	
Kember Flooring, Inc. (also known as Kember Hardwood Flooring, Inc.)	
Kemian Wood Industry (Kunshan) Co., Ltd.	
Kingman Floors Co., Ltd.	
Kingman Wood Industry Co., Ltd.	
Kornbest Enterprises Limited	
Les Planchers Mercier, Inc.	
Linyi Anying Wood Co., Ltd.	
Linyi Youyou Wood Co., Ltd. (successor-in-interest to Shanghai Lizhong Wood Products Co., Ltd.) (a.k.a. The Lizhong Wood Industry Limited Company of Shanghai)	
Logwin Air and Ocean Hong Kong	
Metropolitan Hardwood Floors, Inc.	
Muchsee Wood (Chuzhou) Co., Ltd.	
Pinge Timber Manufacturing (Zhejiang) Co., Ltd.	
Power Dekor Group Co. Ltd.	
Power Dekor North America Inc.	
Riverside Plywood Corporation	
Samling Elegant Living Trading (Labuan) Ltd.	
Samling Global USA, Inc.	
Scholar Home (Shanghai) New Material Co. Ltd.	
Shanghai Lairunde Wood	
Shanghaifloor Timber (Shanghai) Co., Ltd.	
Sino-Maple (Jiangsu) Co., Ltd.	
Suzhou Dongda Wood Co., Ltd.	
Suzhou Times Flooring Co., Ltd.	
Tech Wood International Ltd.	
Tongxiang Jisheng Import and Export Co., Ltd.	
Xiamen Yung De Ornament Co., Ltd.	
Xuzhou Shenghe Wood Co., Ltd.	
Yekalon Industry, Inc.	
Yihua Lifestyle Technology Co., Ltd.	
Yingyi-Nature (Kunshan) Wood Industry Co., Ltd.	
Zhejiang Dadongwu GreenHome Wood Co., Ltd. (a.k.a. Zhejiang Dadongwu Greenhome Wood Co., Ltd. and Zhejiang Dadongwu Green Home Wood Co., Ltd.)	

	Period to be reviewed
Zhejiang Fuerjia Wooden Co., Ltd.	
Zhejiang Jiechen Wood Industry Co., Ltd.	
Zhejiang Longsen Lumbering Co., Ltd.	
Zhejiang Shiyou Timber Co., Ltd.	
Zhejiang Shuimojiangnan New Material Technology Co., Ltd.	
Zhejiang Simite Wooden Co., Ltd.	
Zhejiang Yuhua Timber Co. Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Refillable Stainless Steel Kegs, C–570–094	1/1/20–12/31/20
Equipmentimes (Dalian) E-Commerce Co., Ltd.	
Guangzhou Jingye Machinery Co., Ltd.	
Guangzhou Ulix Industrial & Trading Co., Ltd.	
Jinan HaoLu Machinery Equipment Co., Ltd.	
Jinjiang Jiaxing Import and Export Co., Ltd.	
NDL Keg Qingdao Inc.	
Ningbo All In Brew Technology Co.	
Ningbo BestFriends Beverage Containers Industry Co., Ltd.	
Ningbo Chance International Trade Co., Ltd.	
Ningbo Direct Import & Export Co., Ltd.	
Ningbo Haishu Direct Import and Export Trade Co., Ltd.	
Ningbo Haishu Xiangsheng Metal Factory	
Ningbo Hefeng Container Manufacture Co., Ltd.	
Ningbo Hefeng Kitchen Utensils Manufacture Co., Ltd.	
Ningbo HGM Food Machinery Co., Ltd.	
Ningbo Jiangbei Bei Fu Industry and Trade Co., Ltd.	
Ningbo Kegco International Trade Co., Ltd.	
Ningbo Kegstorm Stainless Steel Co., Ltd.	
Ningbo Master International Trade Co., Ltd.[11]	
Ningbo Minke Import & Export Co., Ltd.	
Ningbo Sanfino Import & Export Co., Ltd.	
Ningbo Shimaotong International Co., Ltd.	
Ningbo Sunburst International Trading Co., Ltd.	
Orient Equipment (Taizhou) Co., Ltd.	
Penglai Jinfu Stainless Steel Products Co., Ltd.	
Pera Industry Shanghai Co., Ltd.	
Qingdao Henka Precision Technology Co., Ltd.	
Qingdao Xinhe Precision Manufacturing Co., Ltd.	
Rain Star International Trading Dalian Co., Ltd.	
Shandong Tiantai Beer Equipment Co., Ltd.	
Shandong Tonsen Equipment Co., Ltd.	
Shandong Yuesheng Beer Equipment Co., Ltd.	
Shenzhen Wellbom Technology Co., Ltd.	
Sino Dragon Group, Ltd.	
Wenzhou Deli Machinery Equipment Co.	
Wuxi Taihu Lamps and Lanterns Co., Ltd.	
Yantai Toptech Ltd.	
Yantai Trano New Material Co., Ltd.	
Suspension Agreements	
MEXICO: Sugar, A–201–845	12/1/20–11/30/21
MEXICO: Sugar, C–201–846	1/1/21–12/31/21

Duty Absorption Reviews

During any administrative review covering all or part of a period falling

[5] Entries of merchandise produced and exported by Shakti Forge Industries Pvt. Ltd. (Shakti) or Shakti Forge are excluded from the antidumping duty order. *See Forged Steel Fittings from India and the Republic of Korea: Antidumping Duty Orders,* 85 FR 80014 (December 11, 2020), as corrected, *Forged Steel Fittings from India and the Republic of Korea: Notice of Correction to the Antidumping Duty and Countervailing Duty Orders,* 85 FR 81876 (December 17, 2020). This initiation notice covers merchandise (1) produced by a third party and exported by Shakti or Shakti Forge, or (2) produced by Shakti or Shakti Forge and exported by a third party.

[6] Commerce deferred the administrative review of Al Jazeera Steel Products Co. SAOG for the period 12/1/2019 through 11/30/2020. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 8166, 8175 (February 4, 2021). As a result of this deferral, Commerce is initiating its review of Al Jazeera Steel Products Co. SAOG covering both the deferred period of review and current period of review.

[7] On November 5, 2021, Commerce initiated the 2020–2021 administrative review of narrow woven ribbons with woven selvedge (ribbons) from Taiwan. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 61121, 61124, as corrected in *Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 67685, 67688 (November 29, 2021). In the notice of initiation, Commerce inadvertently made the following errors: (1) We made a typographical error in the name of one company (*i.e.,* Ethel Enterprise Co., Ltd. Taiwan, listed as Ethel Enterprise Co.); (2) we failed to exclude from the review for Dear Year Brothers Mfg., Co., Ltd ribbons exported by Dear Year Brothers Mfg., Co., Ltd and produced by Dear Year Brothers Mfg., Co., Ltd; Fool Shing Enterprise Co., Ltd.; or Hong Tai Enterprise because ribbons produced and exported by these producer/exporter combinations are not covered by the antidumping duty order. *See Narrow Woven Ribbons with Woven Selvedge from Taiwan and the People's Republic of China: Antidumping Duty Orders,* 75 FR 53632 (Sept. 1, 2010), as amended in *Narrow Woven Ribbons with Woven Selvedge from Taiwan and the People's Republic of China: Amended Antidumping Duty Orders,* 75 FR 56982 (Sept. 17, 2010) (*NWR Taiwan Order*); and (3) we similarly failed to exclude from the review for Shienq Huong Enterprise Co., Ltd.; Hsien Chan Enterprise Co., Ltd.; and Novelty Handicrafts Co., Ltd. (collectively, Shienq Huong) ribbons exported by Shienq Houng and produced by Shieng Houng; Boa Shun Enterprise Co., Ltd.; Chi Hua Textile Corporate Ltd.; Chieng Xin Enterprise Co., Ltd.; Ching Yu Weaving String Corp.; Done Hong Enterprise Co., Ltd.; Guang Xing Zhi Zao Enterprise Co., Ltd.; Hang-Liang Company; Hong-Tai Company; Hua Yi Enterprise Co., Ltd.; Hung Cheng Enterprises Co., Ltd.; Hung Ching Enterprise Co., Ltd.; I Lai Enterprise Co., Ltd.;

Continued

between the first and second or third and fourth anniversary of the publication of an AD order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), Commerce, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether AD duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant ''gap'' period of the order (*i.e.,* the period following the expiry of provisional measures and before definitive measures were put into place), if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with the procedures outlined in Commerce's regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

Commerce's regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). These regulations require any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the *Final Rule,*[12] available at *www.govinfo.gov/content/pkg/FR-2013-07-17/pdf/2013-17045.pdf,* prior to submitting factual information in this segment. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[13]

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information using the formats provided at the end of the *Final Rule.*[14] Commerce intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by Commerce.[15] In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning CBP data; and (5) Q&V questionnaires. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This policy also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the

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Ji Cheng Industry; Le Quan Enterprise Co., Ltd.; Lei Di Si Corporation Ltd.; Oun Mao Co., Ltd.; Shang Yan Gong Yeshe; Sung-Chu Industry; Qiao Zhi Industry; Wei Xin Enterprise Co., Ltd.; Xin Jia Enterprise Co., Ltd.; Yi Chang Corp.; Yi Cheng Gong Ye She; Yi Long Enterprise Co., Ltd.; or Zheng Chi Chi Corp. because ribbons produced and exported by these producer/exporter combinations are not covered by the antidumping duty order. *See NWR Taiwan Order.* Accordingly, we are initiating this administrative review for: (1) Ethel Enterprise Co., Ltd. Taiwan (instead of Ethel Enterprise Co., Ltd.); (2) Dear Year Brothers Mfg., Co., Ltd, but only with respect to subject merchandise exported by Dear Year Brothers Mfg. Co., Ltd. and produced by firms other than Dear Year Brothers Mfg., Co., Ltd; Fool Shing Enterprise Co., Ltd.; or Hong Tai Enterprise; and (3) Shieng Huong, but only with respect to subject merchandise exported by Shieng Huong and produced by firms other than Shieng Houng; Boa Shun Enterprise Co., Ltd.; Chi Hua Textile Corporate Ltd.; Chieng Xin Enterprise Co., Ltd.; Ching Yu Weaving String Corp.; Done Hong Enterprise Co., Ltd.; Guang Xing Zhi Zao Enterprise Co., Ltd.; Hang-Liang Company; Hong-Tai Company; Hua Yi Enterprise Co., Ltd.; Hung Cheng Enterprises Co., Ltd.; Hung Ching Enterprise Co., Ltd.; I Lai Enterprise Co., Ltd.; Ji Cheng Industry; Le Quan Enterprise Co., Ltd.; Lei Di Si Corporation Ltd.; Oun Mao Co., Ltd.; Shang Yan Gong Yeshe; Sung-Chu Industry; Qiao Zhi Industry; Wei Xin Enterprise Co., Ltd.; Xin Jia Enterprise Co., Ltd.; Yi Chang Corp.; Yi Cheng Gong Ye She; Yi Long Enterprise Co., Ltd.; or Zheng Chi Chi Corp.

[8] Commerce inadvertently omitted the China-Wide Entity from the Initiation Notice which published on December 28, 2021 (86 FR 73734).

[9] Commerce received a request for an administrative review with respect to ''Arte Mundi Group Co., Ltd., f/k/a Arte Mundi (Shanghai) Aesthetic Home Furnishings Co., Ltd., f/k/a Scholar Home (Shanghai) New Material Co., Ltd.'' However, Commerce has not determined that Arte Mundi Group Co., Ltd. is the successor-in-interest to Arte Mundi (Shanghai) Aesthetic Home Furnishings Co., Ltd.

[10] Other variations of this company's name are Zhejiang Dadongwu GreenHome Wood Co., Ltd. and Zhejiang Dadongwu Green Home Wood Co., Ltd.

[11] Commerce previously found Ningbo Master International Trade Co., Ltd. to be cross owed with Ningbo Major Draft Beer Equipment Co., Ltd.; Tomorrow Industrial Limited; and Zhejiang Major Technology Co., Ltd. *See Refillable Stainless Steel Kegs from the People's Republic of China: Final Affirmative Countervailing Duty Determination and Final Affirmative Determination of Critical Circumstances, in Part,* 84 FR 57005, 57006 (October 24, 2021).

[12] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* the frequently asked questions regarding the *Final Rule,* available at *https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[13] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 41363 (July 10, 2020).

[14] *See* section 782(b) of the Act; *see also Final Rule;* and the frequently asked questions regarding the *Final Rule,* available at *https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[15] *See* 19 CFR 351.302.

circumstances under which Commerce will grant untimely-filed requests for the extension of time limits. Please review the *Final Rule,* available at *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: January 31, 2022.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2022–02352 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–863]

Large Diameter Welded Pipe From Canada: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that the producers or exporters subject to this administrative review made sales of large diameter welded pipe from the Canada in the United States at prices below normal value (NV) during the period of review (POR), August 27, 2018, through April 30, 2020.

DATES: Applicable February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Irene Gorelik, 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) 482–6905.

SUPPLEMENTARY INFORMATION:

Background

On August 4, 2021, Commerce published the preliminary results of this administrative review.[1] The review covers 40 producers or exporters of subject merchandise. We invited interested parties to comment on the *Preliminary Results.* A summary of the events that occurred since Commerce published the *Preliminary Results,* as well as a full discussion of the issues raised by parties for these final results, are discussed in the Issues and Decision Memorandum.[2]

Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The product covered by this *Order* is large diameter welded pipe from Canada. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.

Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined that Canam (St Gedeon) (Canam),[4] had no shipments during the POR.[5] As we have received no information to contradict this determination, consistent with our practice, we will instruct U.S. Customs and Border Protection (CBP) to liquidate any existing entries of subject merchandise produced by this company, but exported by other parties, at the rate for the intermediate reseller, if available, or at the all-others rate.

Analysis of Comments Received

All issues raised in the parties' case and rebuttal briefs are addressed in the Issues and Decision Memorandum and are listed in Appendix I to this notice.[6] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on comments received from interested parties regarding our *Preliminary Results* and our review of the record to address those comments, we made changes to the *Preliminary Results,* as detailed in the Issues and Decision Memorandum.[7]

Rate for Non-Examined Respondents

As we stated in the *Preliminary Results,* the statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act.[8] For the weighted-average dumping margin for non-examined respondents in an administrative review, generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation.[9] Under section 735(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding rates that are zero, *de minimis,* or based entirely on facts available. For these final results, we calculated a weighted-average dumping margin for Evraz Inc. NA (Evraz), the sole mandatory respondent, that was not zero, *de minimis,* or based entirely on facts available. Accordingly, consistent with our practice, we applied the weighted-average dumping margin calculated for Evraz as the weighted-average dumping margin for the non-examined companies.[10]

Final Results of the Review

As a result of this review, we determine the following weighted-average dumping margins exist for the POR:

[1] *See Large Diameter Welded Pipe from Canada: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2018–2020,* 86 FR 41956 (August 4, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Antidumping Duty Administrative Review: Large Diameter Welded Pipe from Canada; 2018–2020,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See Large Diameter Welded Pipe from Canada: Antidumping Duty Order,* 84 FR 18775 (May 2, 2019) (*Order*).

[4] In the *Initiation Notice,* this company was listed as Canam (St Gedeon). However, in its certification of no shipments, it noted that Canam (St Gedeon) is a plant location and not its legal name. It also noted that it had recently undergone a corporate restructuring and is now named Canam Group Inc., which is the successor entity to Canam Group Inc. f/k/a Canam Buildings and Structures Inc. *See* Canam's Letter, ''No Shipments Letter for Canam Group Inc. f/k/a Canam Buildings and Structures Inc.,'' dated August 7, 2020; *see also Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 41540 (July 10, 2020).

[5] *See Preliminary Results,* 86 FR 41956–57.

[6] *See* Appendix I.

[7] *See* Issues and Decision Memorandum at Comments 2, 3, 5 and 6.

[8] *See Preliminary Results,* 86 FR 41957; *see also* PDM at 4.

[9] *Id.*

[10] *See Preliminary Results,* 86 FR 41957; *see also Narrow Woven Ribbons with Woven Selvedge from Taiwan; Preliminary Results of Antidumping Duty Administrative Review; 2013–2014,* 80 FR 60627, 60627 (October 7, 2015), unchanged in *Narrow Woven Ribbons with Woven Selvedge from Taiwan; Final Results of Antidumping Duty Administrative Review; 2013–2014,* 81 FR 22578 (April 18, 2016); and *Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 80 FR 51779, 51780 (August 26, 2015).

Exporter or producer	Weighted-average dumping margin (percent)
Evraz Inc. NA [11]	15.29
Non-Examined Companies [12]	15.29

Disclosure

Commerce intends to disclose the calculations performed for these final results within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Commerce determined, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with these final results of review.[13]

Pursuant to 19 CFR 351.212(b)(1), as Evraz reported that it is the importer of record for all its U.S. sales and it reported the entered value of those sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of those sales. Where the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce's ''automatic assessment'' practice will apply to entries of subject merchandise during the POR produced by Evraz for which the company did not know that the merchandise it sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[14]

For the companies which were not selected for individual examination, we intend to direct CBP to assess antidumping duties at a rate equal to the weighted-average dumping margin determined for those companies in the final results.

For the company that certified it had no shipments, we will instruct CBP to liquidate any existing entries of subject merchandise produced by it, but exported by other parties, at the rate for the intermediate reseller, if available, or at the all-others rate, consistent with Commerce's reseller policy.[15]

Commerce intends to issue liquidation instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be in effect for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies listed above will be equal to the weighted-average dumping margin that is established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not subject to 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 participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers and exporters will continue to be 12.32 percent *ad valorem,* the all-others rate established in the LTFV investigation.[16]

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: January 28, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Changes to the Preliminary Results
V. Discussion of the Issues
Comment 1: Whether To Apply Partial Adverse Facts Available to Structural Pipe Cost
Comment 2: Whether To Revise Certain Affiliated Supplier Adjustments
Comment 3: Whether To Correct a Clerical Error Regarding Home Market and U.S. Sales

[11] In the underlying less-than-fair-value (LTFV) investigation, Commerce determined that Evraz Inc. NA, Evraz Inc. NA Canada, and the Canadian National Steel Corporation (or Corp.) (collectively, Evraz) comprise a single entity. *See Order.* There is no information on the record of this review that warrants reconsideration of this single entity determination. In the *Preliminary Results,* Commerce inadvertently listed the abbreviated name form ''Canadian National Steel Corp'' in Appendix II as this name form was listed in the *Initiation Notice* separately from the Evraz single entity. As the two names differ only by the abbreviation of Corporation to Corp., we find them to be the same company, and thus, have not listed the abbreviated form in Appendix II of this notice.

[12] *See* Appendix II.

[13] *See* 19 CFR 351.212(b).

[14] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[15] *Id.*

[16] *See Order.*

Comment 4: Whether To Recalculate Home Market Credit Expenses Using Invoice Date
Comment 5: Whether Antidumping Duty Revenue is an Addition to Gross Unit Price
Comment 6: Whether To Cap Movement-Related Revenues by the Corresponding Expenses
Comment 7: Whether Section 232 Duties can be Lawfully Deducted From the Export Price
VI. Recommendation

Appendix II

Companies Not Selected for Individual Examination

1. Aciers Lague Steels Inc
2. Acier Profile SBB Inc
3. Amdor Inc
4. BPC Services Group
5. Bri-Steel Manufacturing
6. Canada Culvert
7. Cappco Tubular Products Canada Inc
8. CFI Metal Inc
9. Dominion Pipe & Piling
10. Enduro Canada Pipeline Services
11. Fi Oilfield Services Canada
12. Forterra
13. Gchem Ltd
14. Graham Construction
15. Groupe Fordia Inc
16. Grupo Fordia Inc
17. Hodgson Custom Rolling
18. Hyprescon Inc
19. Interpipe Inc
20. K K Recycling Services
21. Kobelt Manufacturing Co
22. Labrie Environment
23. Les Aciers Sofatec
24. Lorenz Conveying P
25. Lorenz Conveying Products
26. Matrix Manufacturing
27. MBI Produits De Forge
28. Nor Arc
29. Peak Drilling Ltd
30. Pipe & Piling Sply Ltd
31. Pipe & Piling Supplies
32. Prudental
33. Prudential
34. Shaw Pipe Protecction
35. Shaw Pipe Protection
36. Tenaris Algoma Tubes Facility
37. Tenaris Prudential
38. Welded Tube of Can Ltd

[FR Doc. 2022–02353 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–844]

Certain Carbon and Alloy Steel Cut-to-Length Plate From Germany: Preliminary Results of Antidumping Duty Administrative Review; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that certain carbon and alloy steel cut-to-length plate (CTL plate) from Germany is not being, or is not likely to be, sold in the United States at less than normal value (NV) during the period of review (POR) May 1, 2020, through April 30, 2021.

DATES: Applicable February 4, 2022.

FOR FURTHER INFORMATION CONTACT: David Goldberger, 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) 482–4136.

SUPPLEMENTARY INFORMATION:

Background

On July 6, 2021, based on a timely request for review, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review on CTL plate from Germany.[1] This review covers one producer/exporter of the subject merchandise, AG der Dillinger Hüttenwerke (Dillinger). For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[2]

Scope of the Order [3]

The products covered by the *Order* are certain carbon and alloy steel hot-rolled or forged flat plate products not in coils, whether or not painted, varnished, or coated with plastics or other non-metallic substances from Germany. Products subject to the *Order* are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7225.40.1110, 7225.40.1180, 7225.40.3005, 7225.40.3050, 7226.20.0000, and 7226.91.5000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.[4]

Methodology

Commerce is conducting this review in accordance with sections 751(a)(1)(B) and (2) of the Tariff Act of 1930, as amended (the Act). Export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.* A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice.

Preliminary Results of the Review

As a result of this review, we preliminarily determine that the following weighted-average dumping margin exists for the respondent for the period May 1, 2020, through April 30, 2021:

Producer/exporter	Weighted-average dumping margin (percent)
AG der Dillinger Hüttenwerke	0.00

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice.[5] Interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[6] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the time limit for filing case briefs.[7] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 35481 (July 6, 2021).

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2020–2021 Administrative Review of the Antidumping Duty Order on Certain Carbon and Alloy Steel Cut-To-Length Plate from Germany,'' dated concurrently with, and hereby adopted by this notice (Preliminary Decision Memorandum).

[3] *See Certain Carbon and Alloy Steel Cut-To-Length Plate from Austria, Belgium, France, the Federal Republic of Germany, Italy, Japan, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Determinations for France, the Federal Republic of Germany, the Republic of Korea, and Taiwan, and Antidumping Duty Orders,* 82 FR 24096, 24098 (May 25, 2017) (*Order*).

[4] For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

[5] *See* 19 CFR 351.224(b).

[6] *See* 19 CFR 351.309(c).

[7] Commerce is exercising its discretion, under 19 CFR 351.309(d)(1), to alter the time limit for filing of rebuttal briefs.

with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[8] Case and rebuttal briefs should be filed using ACCESS.[9]

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, U.S. Department of Commerce, filed electronically via ACCESS within 30 days after the date of publication of this notice.[10] Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing.[11] An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[12]

Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless otherwise extended.[13]

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 covered by this review.[14]

If the weighted average dumping margin for Dillinger is not zero or *de minimis* (*i.e.,* less than 0.5 percent), we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[15] If the weighted-average dumping margin for Dillinger is zero or *de minimis* in the final results, or an importer-specific assessment rate is zero or *de minimis* in the final results, we will instruct CBP not to assess antidumping duties on any such entries in accordance with the *Final Modification for Reviews.*[16]

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[17]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the exporter listed above 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* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for companies not participating in this review, the cash deposit rate will continue to be the company-specific cash deposit rate published for the most recently completed segment; (3) if the exporter is not a firm covered in this review, or the less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the cash deposit rate established for the most recently completed segment for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 21.04 percent, the all-others rate established in the LTFV investigation.[18] These deposit requirements, when imposed, shall remain in effect until further notice.

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 review period. 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

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 28, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics 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. 2022–02310 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–122–858]

Certain Softwood Lumber Products From Canada: Preliminary Results, Partial Rescission, and Preliminary Intent To Rescind, in Part, the Countervailing Duty Administrative Review, 2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being

[8] *See* 19 CFR 351.309(c)(2) and (d)(2).

[9] *See* 19 CFR 351.303.

[10] *See* 19 CFR 351.310(c).

[11] *See* 19 CFR 351.310(d).

[12] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020) (Temporary Rule); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[13] *See* section 751(a)(3)(A) of the Act.

[14] *See* 19 CFR 351.212(b).

[15] In these preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[16] *Id.* at 8102.

[17] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[18] *See Order.*

provided to producers and exporters of certain softwood lumber products (softwood lumber) from Canada during the period of review, January 1, 2020, through December 31, 2020. With respect to one company, we are rescinding this administrative review because the request for review was timely withdrawn. Additionally, with respect to 27 companies, we intend to rescind this administrative review. Interested parties are invited to comment on these preliminary results.

DATES: Applicable February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Jonathan Hall-Eastman (Canfor), John Hoffner (JDIL), Kristen Johnson/Samuel Brummitt (Resolute), and Laura Griffith (West Fraser), 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) 482–1468, (202) 482–3315, (202) 482–4793/(202) 482–7851, and (202) 482–6430, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 3, 2018, Commerce published in the **Federal Register** the countervailing duty (CVD) order on softwood lumber from Canada.[1] Several interested parties requested that Commerce conduct an administrative review of the *Order* and, on March 4, 2021, Commerce published in the **Federal Register** a notice of initiation of the third administrative review.[2] On May 5, 2021, we published in the **Federal Register** an additional notice of initiation of an administrative review for two companies that were inadvertently excluded from the March 4, 2021 notice.[3] On April 20, 2021, Commerce selected the following producers and exporters as the mandatory respondents in the administrative review: Canfor Corporation, Resolute FP Canada Inc., and West Fraser Mills Ltd.[4] On September 24, 2021, Commerce selected J.D. Irving, Limited as a voluntary respondent in the administrative review.[5]

On September 2, 2021, Commerce extended the deadline for the preliminary results of this administrative review to January 28, 2022, in accordance with 19 CFR 351.213(h)(2).[6] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[7] 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.*

Scope of the Order

The product covered by this order is certain softwood lumber products from Canada. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

On June 2, 2021, the petitioner[8] timely withdrew its request for an administrative review of Roland Boulanger & Cie Ltee (Roland). No other party requested a review of Roland. Accordingly, we are rescinding this review, in part, with respect to Roland, pursuant to 19 CFR 351.213(d)(1). For further information, *see* ''Partial Recission of Administrative Review'' in the Preliminary Decision Memorandum.

Preliminary Intent To Rescind Administrative Review, in Part

Based on our analysis of U.S. Customs and Border Protection (CBP) data and comments received from interested parties, we preliminarily determine that the following 27 companies had no reviewable shipments, sales, or entries of subject merchandise during the POR:

AA Trading Ltd.
Blanchette & Blanchette Inc.
Canada Pallet Corp.
Careau Bois Inc.
Cedarcoast Lumber Products
Commonwealth Plywood Co. Ltd.
CWP—Montreal inc.
Delta Cedar Specialties Ltd.
Glandell Enterprises Inc.
Goldband Shake & Shingle Ltd.
Greenwell Resources Inc.
Imperial Cedar Products, Ltd.
J.H. Huscroft Ltd.
Langevin Forest Products Inc.
Les Produits Forestiers D&G Ltée (aka, D&G Forest Products Ltd.)
Marcel Lauzon Inc.
North American Forest Products Ltd. (located in Saint-Quentin, New Brunswick)
Sapphire Lumber Company
Scierie Alexandre Lemay & Fils Inc.
Skeena Sawmills Ltd
Sonora Logging Ltd.
Specialiste du Bardeau de Cedre Inc
Suncoast Industries Inc.
Suncoh Custom Lumber Ltd.
Western Timber Products, Inc.
Weston Forest Products Inc.
WWW Timber Products Ltd.

Absent any evidence of shipments placed on the record, pursuant to 19 CFR 351.213(d)(3), we intend to rescind the administrative review of these companies in the final results of review. For further information, *see* ''Preliminary Intent to Rescind Administrative Review, in Part'' in the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this CVD administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that confers a benefit to the recipient, and that the subsidy is specific.[9] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum. The list of topics discussed in the

[1] *See Certain Softwood Lumber Products from Canada: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 83 FR 347 (January 3, 2018) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 12599 (March 4, 2021) (*Initiation Notice*).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 23925 (May 5, 2021).

[4] *See* Memorandum, ''Administrative Review of the Countervailing Duty Order on Certain Softwood Lumber Products from Canada: Respondent Selection,'' dated April 20, 2021.

[5] *See* Commerce's Letter, ''2020 Administrative Review of the Countervailing Duty Order on Certain Softwood Lumber Products from Canada: Selection of JD Irving, Ltd. as a Voluntary Respondent,'' September 24, 2021.

[6] *See* Memorandum, ''Certain Softwood Lumber Products from Canada: Extension of Deadline for Preliminary Results of 2020 Countervailing Duty Administrative Review,'' dated September 2, 2021.

[7] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Administrative Review of the Countervailing Duty Order on Certain Softwood Lumber Products from Canada; 2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[8] The petitioner is the COALITION, an *ad hoc* association whose members are: U.S. Lumber Coalition, Inc.; Collum's Lumber Products, L.L.C.; Fox Lumber Sales, Inc.; Hankins, Inc.; Pleasant River Lumber Company; PotlatchDeltic; Rex Lumber Company; S.I. Storey Lumber Co., Inc.; Stimson Lumber Company; Swanson Group; Weyerhaeuser Company; Carpenters Industrial Council; Giustina Land and Timber Company; and Sullivan Forestry Consultants, Inc.

[9] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

Preliminary Decision Memorandum is included at Appendix I.

Preliminary Rate for Non-Selected Companies Under Review

There are 230 companies for which a review was requested and not rescinded but were not selected as mandatory respondents. The statute and Commerce's regulations do not directly address the establishment of rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation.

Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate an all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters and/or producers individually examined, excluding any zero, *de minimis,* or rates based entirely on facts available. In this review, none of the rates for the respondents were zero, *de minimis,* or based entirely on facts available. Therefore, for the POR, we are assigning to the non-selected companies an average of the subsidy rates calculated for the companies that were selected as respondents in the administrative review.

For further information on the calculation of the non-selected rate, *see* ''Preliminary *Ad Valorem* Rate for Non-Selected Companies under Review'' in the Preliminary Decision Memorandum. For a list of the non-selected companies, *see* Appendix II to this notice.

Preliminary Results of Review

For the period January 1, 2020, through December 31, 2020, we preliminarily determine the following estimated countervailable subsidy rates:

Companies	Subsidy Rate *ad valorem* (percent)
Canfor Corporation and its cross-owned affiliates[10]	1.83
J.D. Irving, Limited and its cross-owned affiliates[11]	2.33
Resolute FP Canada Inc. and its cross-owned affiliates[12]	15.48
West Fraser Mills Ltd. and its cross-owned affiliates[13]	8.46
Non-Selected Companies	6.88

Disclosure

We intend to disclose to parties to this proceeding the calculations performed in these preliminary results within five days of publication of this notice in the **Federal Register**.[14]

Verification

As provided in section 782(i)(3) of the Act, Commerce intends to verify the information relied upon for its final results. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification in this review. Accordingly, we intend to verify the information relied upon for the final results through alternative means in lieu of an on-site verification.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance.[15] A timeline for the submission of case and rebuttal briefs and written comments will be provided to interested parties at a later date. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information until further notice.[16]

Pursuant to 19 CFR 351.309(c) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are requested to submit for each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c)(2), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary for Enforcement and Compliance using ACCESS. Requests should contain the party's name, address, and telephone number; the number of participants; and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm the date and time of the hearing two days before the scheduled date. Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

Final Results

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised by parties in their comments, within 120 days after the date of publication of these preliminary results.

Assessment Rates

In accordance with 19 CFR 351.221(b)(4)(i), Commerce has preliminarily assigned the subsidy rates as indicated above. Pursuant to section 751(a)(2)(C) of the Act, upon issuance of the final results, Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review. For the companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2020, through December 31, 2020, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a). 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 statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

Pursuant to section 751(a)(1) of the Act, Commerce intends, upon

[10] Commerce finds the following companies to be cross-owned with Canfor Corporation: Canadian Forest Products., Ltd. and Canfor Wood Products Marketing, Ltd.

[11] Commerce finds the following companies to be cross-owned with J.D. Irving, Limited: Miramichi Timber Holdings Limited, The New Brunswick Railway Company, Rothesay Paper Holdings Ltd., and St. George Pulp & Paper Limited.

[12] Commerce finds the following companies to be cross-owned with Resolute FP Canada Inc.: Produits Forestiers Maurice SEC. and Resolute Forest Products Inc.

[13] Commerce finds the following companies to be cross-owned with West Fraser Mills Ltd.: West Fraser Timber Co., Ltd., Blue Ridge Lumber Inc., Sunpine Inc., Sundre Forest Products Inc., Manning Forest Products, Ltd., and West Fraser Alberta Holdings, Ltd.

[14] *See* 19 CFR 351.224(b).

[15] *See* 19 CFR 351.309(c) and (d).

[16] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 29615 (May 18, 2020); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts indicated above for each of the respective companies listed above and in Appendix II with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed companies, we will instruct CBP to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

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: January 28, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Review
IV. Partial Rescission of Administrative Review
V. Preliminary Intent to Rescind Administrative Review, in Part
VI. Scope of the *Order*
VII. Subsidies Valuation
VIII. Analysis of Programs
IX. Preliminary *Ad Valorem* Rate for Non-Selected Companies Under Review
X. Programs To Be Addressed After the Preliminary Results
XI. Recommendation

Appendix II

Non-Selected Exporters/Producers

1074712 BC Ltd.
5214875 Manitoba Ltd.
54 Reman
752615 B.C Ltd., Fraserview Remanufacturing Inc., dba Fraserview Cedar Products.
9224–5737 Quebec Inc. (aka A.G. Bois)
Absolute Lumber Products, Ltd.
Adwood Manufacturing Ltd.
Aler Forest Products, Ltd.
All American Forest Products Inc.
Alpa Lumber Mills Inc.
Andersen Pacific Forest Products Ltd.
Anglo-American Cedar Products, Ltd.
Antrim Cedar Corporation
Aquila Cedar Products, Ltd.
Arbec Lumber Inc. (aka Arbec Bois Doeuvre Inc.)
Aspen Planers Ltd.
B&L Forest Products Ltd
B.B. Pallets Inc.
Babine Forest Products Limited
Bakerview Forest Products Inc.
Bardobec Inc.
BarretteWood Inc.
Barrette-Chapais Ltee
Benoit & Dionne Produits Forestiers Ltee
Best Quality Cedar Products Ltd.
Blanchet Multi Concept Inc.
Bois Aise de Montreal Inc.
Bois Bonsai Inc.
Bois Daaquam inc. (aka Daaquam Lumber Inc.)
Bois D'oeuvre Cedrico Inc. (aka Cedrico Lumber Inc.)
Bois et Solutions Marketing SPEC, Inc. (aka SPEC Wood & Marketing Solution or SPEC Wood and Marketing Solutions Inc.)
Boisaco Inc.
Boscus Canada Inc.
Boucher Bros. Lumber Ltd.
BPWood Ltd.
Bramwood Forest Inc.
Brunswick Valley Lumber Inc.
Burrows Lumber (CD) Ltd., Theo A. Burrows Lumber Company Limited (aka Burrows Lumber Inc.)
Busque & Laflamme Inc.
Campbell River Shake & Shingle Co., Ltd.
Canasia Forest Industries Ltd.
Canyon Lumber Company, Ltd.
Carrier & Begin Inc.
Carrier Forest Products Ltd.
Carrier Lumber Ltd.
Carter Forest Products Inc.
Cedar Island Forest Products Ltd.
Cedar Valley Holdings Ltd.
Cedarland Forest Products Ltd.
Cedarline Industries, Ltd.
Central Cedar Ltd.
Central Forest Products Inc.
Centurion Lumber, Ltd.
Chaleur Forest Products Inc.[17]
Chaleur Forest Products LP [18]
Channel-ex Trading Corporation
Clair Industrial Development Corp. Ltd.
Clermond Hamel Ltee
CNH Products Inc.
Coast Mountain Cedar Products Ltd.
Columbia River Shake & Shingle Ltd./Teal Cedar Products Ltd., dba The Teal Jones Group [19]
Comox Valley Shakes (2019) Ltd.
Conifex Fibre Marketing Inc.
Cowichan Lumber Ltd.
CS Manufacturing Inc., dba Cedarshed
CWP—Industriel Inc.
D & D Pallets Ltd.
Dakeryn Industries Ltd.
Decker Lake Forest Products Ltd.
Delco Forest Products Ltd.
Devon Lumber Co. Ltd.
DH Manufacturing Inc.
Direct Cedar Supplies Ltd.
Distribution Rioux Inc.
Doubletree Forest Products Ltd.
Downie Timber Ltd.
Dunkley Lumber Ltd.
EACOM Timber Corporation
East Fraser Fiber Co. Ltd.
Edgewood Forest Products Inc.
Elrod Cartage Ltd.
ER Probyn Export Ltd.
Falcon Lumber Ltd.
Fontaine Inc.
Foothills Forest Products Inc.
Fraser Specialty Products Ltd.
FraserWood Industries Ltd.
Furtado Forest Products Ltd.
Gilbert Smith Forest Products Ltd.
Goldwood Industries Ltd.
Goodfellow Inc.
Gorman Bros. Lumber Ltd.
Greendale Industries Inc.
Griff Building Supplies Ltd.
Groupe Crete Chertsey Inc.
Groupe Crete Division St-Faustin Inc.
Groupe Lebel Inc.
Groupe Lignarex inc.
H.J. Crabbe & Sons Ltd.
Haida Forest Products Ltd.
Hampton Tree Farms, LLC dba Hampton Lumber Sales Canada
Hornepayne Lumber LP
Hudson Mitchell & Sons Lumber Inc.
Hy Mark Wood Products Inc.
Interfor Corporation
Interfor Sales & Marketing Ltd.
Intertran Holdings Ltd. dba Richmond Terminal
Island Cedar Products Ltd
J&G Log Works Ltd.
Jan Woodlands (2001) Inc.
Jasco Forest Products Ltd.
Jazz Forest Products Ltd.
Jhajj Lumber Corporation
Kalesnikoff Lumber Co. Ltd.
Kan Wood, Ltd.
Kebois Ltd (aka Kebois Ltee)
Kelfor Industries Ltd.
Kermode Forest Products Ltd.
Keystone Timber Ltd.
L'Atelier de Readaptation au Travail de Beauce Inc.
Lafontaine Lumber Inc.
Lecours Lumber Co. Limited
Leisure Lumber Ltd.
Les Bardeaux Lajoie Inc.
Les Bois d'oeuvre Beaudoin Gauthier inc.
Les Bois Martek Lumber
Les Bois Traites M.G. Inc.
Les Chantiers de Chibougamau ltd.
Les Industries P.F. Inc.
Leslie Forest Products Ltd.
Lignum Forest Products LLP
Linwood Homes Ltd.
Lonestar Lumber Inc.
Lulumco Inc.
Magnum Forest Products, Ltd.
Maibec inc.
Manitou Forest Products Ltd.
Marwood Ltd.
Materiaux Blanchet Inc.
Mid Valley Lumber Specialties, Ltd.
Midway Lumber Mills Ltd.

[17] In the *Initiation Notice,* we included the company name ''Fornebu Lumber Co. Ltd.'' *See Initiation Notice,* 86 FR at 12608. Subsequently, we determined that the successor-in-interest to Fornebu Lumber Co. Ltd. is Chaleur Forest Products Inc. *See Certain Softwood Lumber Products from Canada: Notice of Final Results of Countervailing Duty Changed Circumstances Review,* 86 FR 43189 (August 6, 2021) (*Chaleur CCR Final*).

[18] In the *Initiation Notice,* we included the company name ''Chaleur Sawmills LP.'' *See Initiation Notice,* 86 FR at 12607. Subsequently, we determined that the successor-in-interest to Chaleur Sawmills LP is Chaleur Forest Products LP. *See Chaleur CCR Final.*

[19] In the *Initiation Notice,* ''Teal Cedar Products Ltd.'' and ''The Teal-Jones Group'' were inadvertently listed separately. *See Initiation Notice,* 86 FR at 12610.

Mill & Timber Products Ltd.
Millar Western Forest Products Ltd.
Mirax Lumber Products Ltd.
Mobilier Rustique (Beauce) Inc.
Monterra Lumber Mills Limited
Morwood Forest Products Inc.
Multicedre ltee
Nakina Lumber Inc.
National Forest Products Ltd.
Nicholson and Cates Ltd
Norsask Forest Products Limited Partnership
North American Forest Products Ltd. (located in Abbotsford, British Columbia)
North Enderby Timber Ltd.
Northland Forest Products Ltd.
Olympic Industries, Inc./Olympic Industries Inc-Reman Code/Olympic Industries ULC/Olympic Industries ULC-Reman/Olympic Industries ULC-Reman Code
Oregon Canadian Forest Products Inc. dba Oregon Canadian Forest Products
Pacific Coast Cedar Products, Ltd.
Pacific Lumber Remanufacturing Inc.
Pacific Pallet, Ltd.
Pacific Western Wood Works Ltd.
PalletSource Inc.
Parallel Wood Products Ltd.
Pat Power Forest Products Corporation
Phoenix Forest Products Inc.
Pioneer Pallet & Lumber Ltd.
Porcupine Wood Products Ltd.
Portbec Forest Products Ltd (aka Les Produits Forestiers Portbec Ltee)
Power Wood Corp.
Precision Cedar Products Corp.
Prendiville Industries Ltd. (aka, Kenora Forest Products)
Produits Forestiers Petit Paris Inc.
Produits forestiers Temrex, s.e.c. (aka Temrex Forest Products LP)
Produits Matra Inc. and Sechoirs de Beauce Inc.
Promobois G.D.S. inc.
Rayonier A.M. Canada GP
Rembos Inc.
Rene Bernard Inc.
Rick Dubois
Rielly Industrial Lumber Inc.
River City Remanufacturing Inc.
S&R Sawmills Ltd
S&W Forest Products Ltd.
San Industries Ltd.
Sawarne Lumber Co. Ltd.
Scierie St-Michel inc.
Scierie West Brome Inc.
Scott Lumber Sales
Shakertown Corp.
Sigurdson Forest Products Ltd.
Silvaris Corporation
Sinclar Group Forest Products Ltd.
Skana Forest Products Ltd.
Source Forest Products
South Beach Trading Inc.
South Coast Reman Ltd.
South Fraser Container Terminals
Spruceland Millworks Inc.
Star Lumber Canada Ltd.
Sundher Timber Products Inc.
Surplus G Rioux
Surrey Cedar Ltd.
Taan Forest Limited Partnership
Taiga Building Products Ltd.
Tall Tree Lumber Company
Terminal Forest Products Ltd.
The Wood Source Inc.
Tolko Industries Ltd. and Tolko Marketing and Sales Ltd.
Trans-Pacific Trading Ltd.
Triad Forest Products Ltd.
Twin Rivers Paper Co. Inc.
Tyee Timber Products Ltd.
Usine Sartigan Inc.
Vaagen Fibre Canada, ULC
Valley Cedar 2 Inc.
Vancouver Specialty Cedar Products Ltd.
Visscher Lumber Inc
W.I. Woodtone Industries Inc.
Waldun Forest Product Sales Ltd.
Watkins Sawmills Ltd.
West Bay Forest Products Ltd.
Western Forest Products Inc.
Western Lumber Sales Limited
Westminster Industries Ltd.
Weyerhaeuser Co.
White River Forest Products L.P.
Winton Homes Ltd.
Woodline Forest Products Ltd.
Woodstock Forest Products
Woodtone Specialties Inc.

[FR Doc. 2022–02322 Filed 2–3–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–073]

Common Alloy Aluminum Sheet From the People's Republic of China: Amended Final Results of Antidumping Duty Administrative Review, 2018–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is amending the final results of the administrative review of the antidumping duty order on common alloy aluminum sheet from the People's Republic of China to correct ministerial errors. The period of review (POR) is June 22, 2018, through January 31, 2020.

DATES: Applicable February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Frank Schmitt or Fred Baker, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4880 or (202) 482–2924, respectively.

Background

On December 27, 2021, Commerce disclosed its calculations for the *Final Results* [1] to interested parties.[2] On January 3, 2022, the domestic industry [3] submitted an allegation of ministerial errors in the *Final Results*.[4] No other party made an allegation of ministerial errors or submitted a reply to the domestic industry's ministerial error allegation.

Legal Framework

Section 751(h) of the Tariff Act of 1930, as amended (the Act), defines a ''ministerial error'' as including ''errors in addition, subtraction, or other arithmetic function, clerical errors resulting from inaccurate copying, duplication, or the like, and any other unintentional error which the administering authority considers ministerial.'' With respect to final results of administrative reviews, 19 CFR 351.224(e) provides that Commerce ''will analyze any comments received and, if appropriate, correct any ministerial error by amending . . . the final results of review . . .''

Ministerial Error

Commerce agrees with the domestic industry that Commerce made inadvertent, unintentional errors in the *Final Results* within the meaning of section 751(h) of the Act and 19 CFR 351.224(f) with respect to its calculation of financial ratios from the financial statement of Alcomet A.B. used in the calculation of normal value for respondent, Jiangsu Alcha Aluminum Co., Ltd., Baotou Alcha Aluminum Co., Ltd., and Alcha International Holdings Limited (collectively, Alcha). Accordingly, Commerce determines that, in accordance with section 751(h) of the Act and 19 CFR 351.224(f), it made ministerial errors in the *Final Results*.

For a complete discussion of the ministerial error allegation, as well as Commerce's analysis, *see* the accompanying Ministerial Error Memorandum.[5] The Ministerial Error Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and

[1] *See Common Alloy Aluminum Sheet from the People's Republic of China: Final Results of Antidumping Duty Administrative Review, Final Successor-In-Interest Determination, and Final Determination of No Shipments; 2018–2020,* 86 FR 74066 (December 29, 2021) (*Final Results*).

[2] *See* Memorandum, ''Common Alloy Aluminum Sheet from the People's Republic of China, 2018–2020: Final Results Disclosure,'' dated December 27, 2021.

[3] The domestic industry is the Aluminum Association Common Alloy Aluminum Sheet Trade Enforcement Working Group and its individual members.

[4] *See* Domestic Industry's Letter, ''1st Administrative Review of the Antidumping Order on Common Alloy Aluminum Sheet from the People's Republic of China—Domestic Industry's Comments Identifying a Ministerial Error in Final Results,'' dated January 3, 2022.

[5] *See* Memorandum, ''Administrative Review of the Antidumping Duty Order on Common Alloy Aluminum Sheet from the People's Republic of China: Ministerial Error Allegation in the Final Results,'' dated concurrently with this notice (Ministerial Error Memorandum).

Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.*

Pursuant to 19 CFR 351.224(e), Commerce is amending the *Final Results* to reflect the correction of a ministerial error in the calculation of the weighted-average dumping margin assigned to Alcha in the *Final Results,* which changes from 56.93 percent to 58.61 percent. Furthermore, we are revising the dumping margin applicable to the company not selected for individual examination in this administrative review, Yinbang Clad Material Co., Ltd. (Yinbang Clad), which is based entirely on Alcha's weighted-average dumping margin.[6]

Amended Final Results

As a result of correcting the ministerial errors, Commerce determines that the following weighted-average dumping margins exist for the period June 22, 2018, through January 31, 2020:

Exporter	Weighted-average dumping margin (percent)
Jiangsu Alcha Aluminum Co., Ltd.[7]/Baotou Alcha Aluminum Co., Ltd./Alcha International Holdings Limited	58.61
Yinbang Clad Material Co., Ltd.	58.61

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after publication of these amended final results in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with these amended final results of review. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results. 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).

Where Alcha reported reliable entered values, we calculated importer- (or customer-) specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer).[8] Where Commerce calculated a weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to that party by the total sales quantity associated with those transactions, Commerce will direct CBP to assess importer- (or customer-) specific assessment rates based on the resulting per-unit rates.[9] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is greater than *de minimis* (*i.e.,* 0.50 percent), Commerce will instruct CBP to collect the appropriate duties at the time of liquidation.[10] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[11]

For the non-selected respondent that received a separate rate, Yinbang Clad, we will instruct CBP to apply an antidumping duty assessment rate of 58.61 percent to all entries of subject merchandise that entered the United States during the POR. For the companies that we determined had no reviewable entries of the subject merchandise in this review period, any suspended entries that entered under those exporters' case numbers (*i.e.,* at the exporters' rates) will be liquidated at the China-wide rate, *i.e.,* 59.72 percent.[12] For all other companies, we will instruct CBP to apply the antidumping duty assessment rate of the China-wide entity to all entries of subject merchandise exported by these companies.[13]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For subject merchandise exported by the companies listed above that have separate rates, the cash deposit rate will be the rate established in these final results of review for each exporter as listed above; (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, except for the companies which lost their separate rate eligibility in this review, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, or lost their separate rate eligibility in this review, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a 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). 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.

[6] *See Final Results,* 86 FR at 74067.

[7] For the purposes of this review, we have considered the names Jiangsu Alcha Aluminum Co., Ltd. and Jiangsu Alcha Aluminium Co., Ltd., as equivalent.

[8] *See* 19 CFR 351.212(b)(1).

[9] *Id.*

[10] *Id.*

[11] *See* 19 CFR 351.106(c)(2).

[12] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[13] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 19730, 19731 (April 8, 2020) (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.'').

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(h) and 777(i)(1) of the Act, and 19 CFR 351.224(e).

Dated: January 31, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–02351 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–857]

Certain Softwood Lumber Products From Canada: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty (AD) order on certain softwood lumber products (softwood lumber) from Canada. The period of review (POR) is January 1, 2020, through December 31, 2020. Commerce preliminarily determines that the producers/exporters subject to this review made sales of subject merchandise at less than normal value. We invite interested parties to comment on these preliminary results.

DATES: Applicable February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen (Canfor) and Maisha Cryor (West Fraser), AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2769 and (202) 482–5831, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 4, 2021, based on timely requests for administrative reviews, Commerce initiated an AD administrative review covering 275 companies and has not rescinded the review of any of these companies.[1] Thus, the review covers 275 producers/exporters of the subject merchandise, including mandatory respondents Canfor [2] and West Fraser.[3] The remaining companies were not selected for individual examination and remain subject to this administrative review. On September 8, 2021, we extended the preliminary results until January 28, 2022.[4]

Scope of the Order

The product covered by this review is softwood lumber from Canada. For a full description of the scope, *see* the Preliminary Decision Memorandum.[5]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of the topics is included in the Preliminary Decision Memorandum as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be found at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of the Administrative Review

We preliminarily determine that the following weighted-average dumping margins exist for the period January 1, 2020, through December 31, 2020:

Exporter/producer	Weighted-average margin (percent)
Canfor Corporation/Canadian Forest Products Ltd./Canfor Wood Products Marketing Ltd	4.92
West Fraser Mills Ltd./Blue Ridge Lumber Inc./Manning Forest Products Ltd./and Sundre Forest Products Inc	4.63
Non-Selected Companies	4.76

Rate for Companies Not Individually Examined

Generally, when calculating margins for non-selected respondents, Commerce looks to section 735(c)(5) of the Act for guidance, which provides instructions for calculating the all-others margin in an investigation. Section 735(c)(5)(A) of the Act provides that when calculating the all-others margin, Commerce will exclude any zero and *de minimis* weighted-average dumping margins, as well as any weighted-average dumping margins based on total facts available. Accordingly, Commerce's usual practice has been to average the margins for selected respondents, excluding margins that are zero, *de minimis,* or based entirely on facts available.

In this review, we calculated a weighted-average dumping margin of 4.92 percent for Canfor and 4.63 percent for West Fraser. In accordance with section 735(c)(5)(A) of the Act, Commerce assigned the weighted average of these two calculated weighted-average dumping margins based on their publicly ranged sales data, 4.76 percent, to the non-selected companies in these preliminary results.[6]

Disclosure

We intend to disclose the calculations performed for these preliminary results to the interested parties within five days after public announcement of the preliminary results in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 12599 (March 4, 2021) (*Initiation Notice*).

[2] As described in the Preliminary Decision Memorandum, we have treated Canfor Corporation, Canadian Forest Products Ltd., and Canfor Wood Products Marketing Ltd. (collectively, Canfor) as a single entity. *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Softwood Lumber Products from Canada; 2019,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum) at 5.

[3] As described in the Preliminary Decision Memorandum, we have treated West Fraser Mills Ltd., Blue Ridge Lumber Inc., Manning Forest Products Ltd., and Sundre Forest Products Inc. (collectively, West Fraser) as a single entity. *See* Preliminary Decision Memorandum at 5.

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review—2020,'' dated September 8, 2021.

[5] *See* Preliminary Decision Memorandum at 3–4.

[6] *See* Memorandum, ''Calculation of the Rate for Non-Selected Respondents,'' dated concurrently with this notice. A list of the non-selected companies under review is included as Attachment II.

COVID–19 pandemic, Commerce is unable to conduct on-site verification in this review. Accordingly, we intend to verify the information relied upon in making the final determination through alternative means in lieu of an on-site verification.

Public Comment

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to the Assistant Secretary for Enforcement and Compliance not later than 30 days after the date of publication of this notice, unless Commerce alters the time limit. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[7] Parties who submit case briefs or rebuttal briefs in this administrative review are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[8] Commerce has modified certain of its requirements for service of documents containing business proprietary information, until further notice.[9]

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 ACCESS. An electronically filed document must be received successfully in its entirety via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[10] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act, unless extended.

Assessment Rate

Upon issuance of the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[11] If a respondent's weighted-average dumping margin is above *de minimis* in the final results of this review, we will calculate an importer-specific assessment rate based on the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of the sales in accordance with 19 CFR 351.212(b)(1).[12] If a respondent's weighted-average dumping margin or an importer-specific assessment rate is zero or *de minimis* in the final results of review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with the *Final Modification for Reviews*.[13] The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise under review and for future deposits of estimated duties, where applicable. We intend to issue liquidation instructions to CBP no earlier than 41 days after date of publication of the final results of this review in the **Federal Register**.

Cash Deposit Requirements

The following cash deposit requirements for estimated antidumping duties will be effective upon publication of the notice of final results of this review for all shipments of softwood lumber from Canada entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for companies subject to this review will be equal to the dumping margin established in the final results of the review; (2) for merchandise exported by companies not covered in this review but covered in a prior segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value (LTFV) investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be the 6.04 percent, the all-others rate established in the LTFV investigation.[14] These cash deposit requirements, when imposed, shall remain in effect until further notice.

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 period of review. 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

Commerce is issuing and publishing these results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(4).

Dated: January 28, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Affiliation and Collapsing of Affiliates
V. Particular Market Situation Allegation
VI. Unexamined Respondents
VII. Discussion of the Methodology
VIII. Recommendation

Appendix II

Non-Selected Companies Under Review

1. 1074712 BC Ltd.
2. 5214875 Manitoba Ltd.
3. 54 Reman
4. 752615 B.C Ltd. Fraserview Remanufacturing Inc., (dba Fraserview Cedar Products)
5. 9224–5737 Quebec inc. (aka A.G. Bois)
6. AA Trading Ltd.
7. Absolute Lumber Products Ltd.
8. Adwood Manufacturing Ltd
9. Aler Forest Products Ltd.
10. All American Forest Products Inc.
11. Alpa Lumber Mills Inc.
12. Andersen Pacific Forest Products Ltd.
13. Anglo American Cedar Products Ltd.
14. Antrim Cedar Corporation
15. Aquila Cedar Products Ltd.
16. Arbec Lumber Inc.
17. Aspen Planers Ltd.
18. B&L Forest Products Ltd.
19. Babine Forest Products Limited

[7] *See* 19 CFR 351.309(d); *see also* 19 CFR 351.303 (for general filing requirements).

[8] *See* 19 CFR 351.309(c)(2) and (d)(2).

[9] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[10] *See* 19 CFR 351.310(c).

[11] *See* 19 CFR 351.212(b).

[12] In these preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012) (*Final Modification for Reviews*).

[13] *See Final Modification for Reviews,* 77 FR at 8103; *see also* 19 CFR 351.106(c)(2).

[14] *See Certain Softwood Lumber Products From Canada: Antidumping Duty Order and Partial Amended Final Determination,* 83 FR 350 (January 3, 2018).

20. Bakerview Forest Products Inc.
21. Bardobec Inc.
22. Barrette-Chapais Ltee
23. BarretteWood Inc.
24. Benoît & Dionne Produits Forestiers Ltée (aka Benoît & Dionne Forest Products Ltd.)
25. Best Quality Cedar Products Ltd.
26. Blanchet Multi Concept Inc.
27. Blanchette & Blanchette Inc.
28. Bois Aisé de Montréal Inc.
29. Bois Bonsaï inc.
30. Bois D'Oeuvre Cedrico Inc. (aka Cedrico Lumber Inc.)
31. Bois Daaquam Inc.
32. Bois et Solutions Marketing SPEC, Inc.
33. Boisaco Inc.
34. Boscus Canada Inc.
35. Boucher Bros. Lumber Ltd.
36. BPWood Ltd.
37. Bramwood Forest Inc.
38. Brink Forest Products Ltd.
39. Brunswick Valley Lumber Inc.
40. Burrows Lumber (CD) Ltd., Theo A. Burrows Lumber Company Limited
41. Busque & Laflamme Inc.
42. Campbell River Shake & Shingle Co. Ltd.
43. Canada Pallet Corp.
44. Canasia Forest lndustries Ltd.
45. Canyon Lumber Company Ltd.
46. Careau Bois Inc.
47. Carrier & Bégin Inc.
48. Carrier Forest Products Ltd.
49. Carrier Lumber Ltd.
50. Carter Forest Products Inc.
51. Cedar Island Forest Products Ltd.
52. Cedar Valley Holdings Ltd.
53. Cedarcoast Lumber Products
54. Cedarland Forest Products Ltd.
55. Cedarline Industries Ltd.
56. Central Cedar Ltd.
57. Central Forest Products Inc.
58. Centurion Lumber Ltd.
59. Chaleur Sawmills LP/Chaleur Forest Products LP [15]
60. Channel-ex Trading Corporation
61. Clair Industrial Development Corp. Ltd.
62. Clermond Hamel Ltee
63. CNH Products Inc.
64. Coast Clear Wood Ltd.
65. Coast Mountain Cedar Products Ltd.
66. Commonwealth Plywood Co. Ltd.
67. Conifex Fibre Marketing Inc.
68. Coulson Manufacturing Ltd.
69. Cowichan Lumber Ltd.
70. CS Manufacturing Inc. (dba Cedarshed)
71. CWP—Industriel Inc.
72. CWP—Montréal Inc.
73. D & D Pallets Ltd.
74. Dakeryn Industries Ltd.
75. Decker Lake Forest Products Ltd.
76. Deep Cove Forest Products, Inc.
77. Delco Forest Products Ltd.
78. Delta Cedar Specialties Ltd.
79. Devon Lumber Co. Ltd.
80. DH Manufacturing Inc.
81. Direct Cedar Supplies Ltd.
82. Distribution Rioux Inc.
83. Doubletree Forest Products Ltd.
84. Downie Timber Ltd.
85. Dunkley Lumber Ltd.
86. EACOM Timber Corporation
87. East Fraser Fiber Co. Ltd.
88. Edgewood Forest Products Inc.
89. Elrod Cartage Ltd.
90. ER Probyn Export Ltd.
91. Falcon Lumber Ltd.
92. Fontaine Inc.
93. Foothills Forest Products Inc.
94. Fornebu Lumber Company Inc./Chaleur Forest Products Inc.[16]
95. Fraser Specialty Products Ltd.
96. FraserWood Industries Ltd
97. Furtado Forest Products Ltd.
98. Glandell Enterprises Inc.
99. Goldband Shake & Shingle Ltd.
100. Goldwood Industries Ltd.
101. Goodfellow Inc.
102. Gorman Bros. Lumber Ltd.
103. Greendale Industries Inc.
104. Greenwell Resources Inc.
105. Griff Building Supplies Ltd.
106. Groupe Crête Chertsey Inc.
107. Groupe Crête Division St-Faustin Inc.
108. Groupe Lebel Inc.
109. Groupe Lignarex Inc.
110. H.J. Crabbe & Sons Ltd.
111. Haida Forest Products Ltd.
112. Halo Sawmill, a division of Delta Cedar Specialties Ltd.
113. Hampton Tree Farms, LLC (dba Hampton Lumber Sales Canada)
114. Hornepayne Lumber LP
115. Hudson Mitchell & Sons Lumber Inc.
116. Hy Mark Wood Products Inc.
117. Imperial Cedar Products Ltd.
118. Independent Building Materials Distribution Inc.
119. Interfor Corporation
120. Interfor Sales & Marketing Ltd.
121. Intertran Holdings Ltd. (dba Richmond Terminal)
122. Island Cedar Products Ltd.
123. J&G Log Works Ltd.
124. Jan Woodlands (2001) Inc.
125. Jasco Forest Products Ltd.
126. Jazz Forest Products Ltd.
127. J.H. Huscroft Ltd.
128. Jhajj Lumber Corporation
129. Kalesnikoff Lumber Co. Ltd.
130. Kan Wood Ltd.
131. Kébois Ltée
132. Kelfor Industries Ltd.
133. Kermode Forest Products Ltd.
134. Keystone Timber Ltd.
135. L'Atelier de Réadaptation au Travil de Beauce Inc.
136. Lafontaine Lumber Inc.
137. Langevin Forest Products Inc.
138. Lecours Lumber Co. Limited
139. Leisure Lumber Ltd.
140. Les Bardeaux Lajoie Inc.
141. Les Bois d'oeuvre Beaudoin Gauthier Inc.
142. Les Bois Martek Lumber
143. Les Bois Traités M.G. Inc.
144. Les Chantiers de Chibougamau Ltée
145. Les Industries P.F. Inc.
146. Les Palettes B.B.Inc. (aka B.B.Pallets Inc.)
147. Les Produits Forestiers D&G Ltée (aka D&G Forest Products Ltd.)
148. Leslie Forest Products Ltd.
149. Lignum Forest Products LLP
150. Linwood Homes Ltd.
151. Lonestar Lumber lnc.
152. Lulumco inc.
153. Magnum Forest Products, Ltd.
154. Maibec inc.
155. Mainland Sawmill, a division of Terminal Forest Products
156. Manitou Forest Products Ltd.
157. Marcel Lauzon Inc.
158. Marwood Ltd.
159. Materiaux Blanchet Inc.
160. Mid Valley Lumber Specialties Ltd.
161. Midway Lumber Mills Ltd.
162. Mill & Timber Products Ltd.
163. Millar Western Forest Products Ltd.
164. Mirax Lumber Products Ltd.
165. Mobilier Rustique (Beauce) Inc.
166. Monterra Lumber Mills Limited
167. Morwood Forest Products Inc.
168. Multicedre Itee
169. Nakina Lumber Inc.
170. National Forest Products Ltd.
171. Nicholson and Cates Ltd
172. Nickel Lake Lumber
173. Norsask Forest Products Inc.
174. Norsask Forest Products Limited Partnership
175. North American Forest Products Ltd. (located in Saint-Quentin, New Brunswick)
176. North American Forest Products, Ltd. (located in Abbotsford, British Columbia)
177. North Enderby Timber Ltd.
178. Northland Forest Products Ltd.
179. Olympic Industries Inc-Reman Codes
180. Olympic Industries ULC
181. Olympic Industries ULC-Reman
182. Olympic Industries ULC-Reman Code
183. Olympic Industries, Inc.
184. Oregon Canadian Forest Products Inc. d.b.a. Oregon Canadian Forest Products
185. Pacific Coast Cedar Products Ltd.
186. Pacific Lumber Remanufacturing Inc.
187. Pacific Pallet, Ltd.
188. Pacific Western Wood Works Ltd.
189. PalletSource Inc.
190. Parallel Wood Products Ltd.
191. Pat Power Forest Products Corporation
192. Phoenix Forest Products Inc.
193. Pine Ideas Ltd.
194. Pioneer Pallet & Lumber Ltd.
195. Porcupine Wood Products Ltd.
196. Portbec Forest Products Ltd./Les

[15] In the *Initiation Notice,* we included the company name ''Chaleur Sawmills LP.'' *See Initiation Notice* at 86 FR 12602. Subsequently, we determined that the successor-in-interest to Chaleur Sawmills LP is Chaleur Forest Products LP. *See Certain Softwood Lumber Products from Canada: Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 86 FR 22934 (April 30, 2021), and accompanying Preliminary Decision Memorandum, unchanged in *Certain Softwood Lumber Products from Canada: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 86 FR 33222 (June 24, 2021) (*Chaleur CCR).* We intend to liquidate all entries by Chaleur Sawmills LP based on the final results, but revise the cash deposit rate for Chaleur Forest Products LP.

[16] In the *Initiation Notice,* we included the company name ''Fornebu Lumber Company Inc.'' *See Initiation Notice* at 86 FR 12602. On February 11, 2021, Fornebu Lumber Company Inc. stated that it had incorrectly identified itself as Fornebu Lumber Co. Ltd. but that they are the same company. *See* Fornebu Lumber Company Inc. Letter, ''Clarification of Company Name of Fornebu Lumber Company Inc.,'' dated February 11. 2021. Subsequently, we determined that the successor-in-interest to Fornebu Lumber Co. Ltd. (and Fornebu Lumber Company Inc.) is Chaleur Forest Products Inc. *See Chaleur CCR.* We intend to liquidate all entries by Fornebu Lumber Company Inc. based on the final results, but revise the cash deposit rate for Chaleur Forest Products Inc.

Produits Forestiers Portbec Ltée
197. Power Wood Corp.
198. Precision Cedar Products Corp.
199. Prendiville Industries Ltd. (aka Kenora Forest Products)
200. Produits Forestiers Petit Paris Inc.
201. Produits forestiers Temrex, s.e.c.
202. Produits Matra Inc.
203. Promobois G.D.S. Inc.
204. Rayonier A.M. Canada GP
205. Rembos Inc.
206. René Bernard Inc.
207. Resolute Growth Canada Inc.; Forest Products Mauricie LP, Société en commandite Scierie Opitciwan; Resolute-LP Engineered Wood Larouche Inc.; Resolute-LP Engineered Wood St-Prime Limited Partnership; Resolute FP Canada Inc.
208. Rick Dubois
209. Rielly Industrial Lumber Inc.
210. River City Remanufacturing Inc.
211. S&R Sawmills Ltd.
212. S&W Forest Products Ltd.
213. San Industries Ltd.
214. Sapphire Lumber Company
215. Sawarne Lumber Co. Ltd.
216. Scierie Alexandre Lemay & Fils Inc.
217. Scierie St-Michel Inc.
218. Scierie West Brome Inc.
219. Scott Lumber Sales
220. Sechoirs de Beauce Inc.
221. Shakertown Corp.
222. Sigurdson Forest Products Ltd.
223. Silvaris Corporation
224. Sinclar Group Forest Products Ltd.
225. Skana Forest Products Ltd.
226. Skeena Sawmills Ltd.
227. Sonora Logging Ltd.
228. Source Forest Products
229. South Beach Trading Inc.
230. South Coast Reman Ltd.
231. South Fraser Container Terminals
232. Specialiste du Bardeau de Cedre Inc.
233. Spruceland Millworks Inc.
234. Star Lumber Canada Ltd.
235. Suncoast Industries Inc.
236. Suncoh Custom Lumber Ltd.
237. Sundher Timber Products Inc.
238. Surplus G Rioux
239. Surrey Cedar Ltd.
240. Taan Forest Limited Partnership
241. Taiga Building Products Ltd.
242. Tall Tree Lumber Company
243. Teal Cedar Products Ltd.
244. Terminal Forest Products Ltd.
245. The Teal Jones Group
246. The Wood Source Inc.
247. Tolko Marketing and Sales Ltd., Tolko Industries Ltd., and Gilbert Smith Forest Products Ltd.
248. Trans-Pacific Trading Ltd.
249. Triad Forest Products Ltd.
250. Twin Rivers Paper Co. Inc.
251. Tyee Timber Products Ltd.
252. Usine Sartigan Inc.
253. Vaagen Fibre Canada ULC
254. Valley Cedar 2 Inc.
255. Vancouver Specialty Cedar Products Ltd.
256. Vanderhoof Specialty Wood Products Ltd.
257. Visscher Lumber Inc.
258. W.I. Woodtone Industries Inc.
259. Waldun Forest Product Sales Ltd.
260. Watkins Sawmills Ltd.
261. West Bay Forest Products Ltd.
262. Western Forest Products Inc.
263. Western Lumber Sales Limited
264. Western Timber Products, Inc.
265. Westminster Industries Ltd.
266. Weston Forest Products Inc.
267. Weyerhaeuser Co.
268. White River Forest Products L.P.
269. Winton Homes Ltd.
270. Woodline Forest Products Ltd.
271. Woodstock Forest Products
272. Woodtone Specialties Inc.
273. WWW Timber Products Ltd.

[FR Doc. 2022–02321 Filed 2–3–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–820]

Prestressed Concrete Steel Wire Strand From Thailand: Preliminary Results of Antidumping Duty Administrative Review; 2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that prestressed concrete steel wire strand (PC strand) from Thailand was sold in the United States at less than normal value (NV) during the period of review of January 1, 2020, through December 31, 2020.

DATES: Applicable February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Max Goldman 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) 482–3896 or (202) 482–1766, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 28, 2004, Commerce published in the **Federal Register** the antidumping duty (AD) order on PC strand from Thailand.[1] Commerce initiated this administrative review on February 26, 2021.[2] This review covers one company, The Siam Industrial Wire Co., Ltd. (SIW). On May 25, 2021, Thai Wire Products Public Company Limited (Thai Wire Company) timely withdrew its request for review with respect to itself.[3] Based on this timely withdrawal and the fact that no other party requested review of this company, we rescinded this review with respect to Thai Wire Company, in accordance with 19 CFR 351.213(d)(1).[4]

On September 10, 2021, we extended the deadline for the preliminary results of this review to January 28, 2022.[5] For a detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[6]

Scope of the Order

The merchandise covered by the *Order* is PC strand from Thailand. Products subject to the *Order* are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7312.10.3010 and 7312.10.3012. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive. 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) of the Tariff Act of 1930, as amended (the Act). Constructed export price was calculated in accordance with section 772 of the Act. NV is 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 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 *http://access.trade.gov.* In addition, a complete

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Prestressed Concrete Steel Wire Strand from Thailand,* 69 FR 4111 (January 28, 2004) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 12599 (March 4, 2021) (*Initiation Notice*).

[3] *See* Thai Wire Company's Letter, ''Administrative Review Withdrawal,'' dated May 25, 2021.

[4] *See Prestressed Concrete Steel Wire Strand from Thailand: Partial Rescission of Antidumping Duty Administrative Review; 2020,* 86 FR 33231 (June 24, 2021).

[5] *See* Memorandum, ''Prestressed Concrete Steel Wire Strand from Thailand: Extension of Deadline for Preliminary Results of 2020 Antidumping Duty Administrative Review,'' dated September 10, 2021.

[6] *See* Memorandum, ''Prestressed Concrete Steel Wire Strand from Thailand: Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review; 2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

version of the Preliminary Decision Memorandum can be accessed at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results

We preliminarily determine the following weighted-average dumping margin for the period January 1, 2020, through December 31, 2020:

Exporter/producer	Weighted-average dumping margin (percent)
The Siam Industrial Wire Co. Ltd	0.98

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). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, 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.[7] 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.[8] Case and rebuttal briefs should be filed using ACCESS [9] and must be served on interested parties.[10] Executive summaries should be limited to five pages total, including footnotes.

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, U.S. Department of Commerce, filed electronically via Commerce's electronic records system, ACCESS, within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) 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.[11] 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 [12] and must be served on interested parties.[13] 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. Commerce has modified certain of its requirements for serving documents containing business proprietary information until further notice.[14]

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.[15]

Assessment Rates

Upon completion of the final results of this administrative review, Commerce shall determine, and U.S Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries.[16] If SIW'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 given that SIW reported entered values, we intend to 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 sales, in accordance with 19 CFR 351.212(b)(1). We intend to instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.,* 0.50 percent). Where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of review, we intend to instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2). If SIW's weighted-average dumping margin is zero or *de minimis* in the final results of review, we intend to instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews*.[17]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by SIW for which it did not know that the merchandise was destined for the United States, we intend to instruct CBP to liquidate those entries at the all-others rate in the original less-than-fair-value (LTFV) investigation (as amended) [18] if there is no rate for the intermediate company(ies) involved in the transaction.[19] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this administrative review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for SIW will be that established in the final results of this administrative review, except if the rate is less than 0.50 percent, and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not participating in this review, the cash deposit will continue to be the company-specific cash deposit rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or the underlying investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding

[7] *See* 19 CFR 351.309(d)(1) and (2); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[8] *See* 19 CFR 351.309(c)(2) and (d)(2).

[9] *See generally* 19 CFR 351.303.

[10] *See* 19 CFR 351.303(f).

[11] *See* 19 CFR 351.310(d).

[12] *See* 19 CFR 351.303.

[13] *See* 19 CFR 351.303(f).

[14] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID 19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[15] *See* section 751(a)(3)(A) of the Act; and 19 CFR 351.213(h).

[16] *See* 19 CFR 351.212(b)(1).

[17] *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) (*Final Modification for Reviews*) (''Where the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis,* no antidumping duties will be assessed.'').

[18] *See Order.*

[19] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 12.91 percent, the all-others rate established in the LTFV investigation (as amended).[20] These deposit requirements, when imposed, shall remain in effect until further notice.

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

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: January 28, 2022.

Lisa W. Wang,

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. 2022–02324 Filed 2–3–22; 8:45 am]

BILLING CODE 3510–DS–P

[20] *See Order.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Public Meeting of the Ocean Exploration Advisory Board

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda for a meeting of the Ocean Exploration Advisory Board (OEAB). OEAB members will discuss and provide advice on Federal ocean exploration programs, with a particular emphasis on the topics identified in the section on Matters to Be Considered.

DATES: The announced meeting is scheduled for Thursday, February 17, 2022 from 9:00 a.m.–5:00 p.m. (EST) and Friday February 18, 2022 from 9:00 a.m.–1:00 p.m. (EST).

ADDRESSES: This will be an in-person meeting. The meeting will be held at the Woods Hole Oceanographic Institution at 86 Water St., Falmouth, MA 02543. Information about how to participate, including Covid-19 related protocols, will be posted to the OEAB website at *https://oeab.noaa.gov/.*

FOR FURTHER INFORMATION CONTACT: Mr. David Turner, Designated Federal Officer, Ocean Exploration Advisory Board, National Oceanic and Atmospheric Administration, *david.turner@noaa.gov* or (859) 327–9661.

SUPPLEMENTARY INFORMATION: NOAA established the OEAB under the Federal Advisory Committee Act (FACA) and legislation that gives the agency statutory authority to operate an ocean exploration program and to coordinate a national program of ocean exploration. The OEAB advises NOAA leadership on strategic planning, exploration priorities, competitive ocean exploration grant programs, and other matters as the NOAA Administrator requests.

OEAB members represent government agencies, the private sector, academic institutions, and not-for-profit institutions involved in all facets of ocean exploration—from advanced technology to citizen exploration.

In addition to advising NOAA leadership, NOAA expects the OEAB to help to define and develop a national program of ocean exploration—a network of stakeholders and partnerships advancing national priorities for ocean exploration.

Matters To Be Considered: The OEAB will hear updates from NOAA Ocean Exploration about (1) the status of recommendations for improving Grant Program; (2) the status of NOAA's buildout of a new dedicated ocean exploration vessel; (3) the status of NOAA Ocean Exploration's FY22–27 Strategic Plan; and (4) the status of planning coordinated exploration activities in the Pacific Ocean. The Board will also hear presentations from several subject matter experts about data, technology, and operational requirements that may influence the future of Ocean Exploration. Portions of the meeting may be partially closed to the public based upon provisions of the Government in the Sunshine Act of 1976 (Pub. L. 94–409). The agenda and other meeting materials will be made available on the OEAB website at *https://oeab.noaa.gov/.*

Status: The meeting will be open to the public with a 15-minute public comment period on Friday, February 18, 2022, from 12:30 p.m.–12:45 p.m. (EST). (Please check the final agenda on the OEAB website to confirm the time). The public may listen to the meeting and provide comments during the public comment period via teleconference. Participation information will be on the meeting agenda on the OEAB website.

The OEAB expects that public statements at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to three minutes. The Designated Federal Officer must receive written comments by February 10, 2022, to provide sufficient time for OEAB review. Written comments received after February 10, 2022, will be distributed to the OEAB but may not be reviewed prior to the meeting date. Comments should be submitted to Designated Federal Officer *David.Turner@noaa.gov.*

Special Accomodations: Requests for sign language interpretation or other auxiliary aids should be directed to the Designated Federal Officer by February 10, 2022.

Eric Locklear,

Acting Chief Financial Officer/Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–02005 Filed 2–3–22; 8:45 am]

BILLING CODE 3510–KA–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB778]

Marine Mammals; File No. 22187

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

ACTION: Notice; withdrawal of application; receipt of application for permit amendment.

SUMMARY: Notice is hereby given that Heather E. Liwanag, Ph.D., 1 Grand Avenue, San Luis Obispo, CA 93407–0401, has withdrawn her application for a major amendment and has applied for a revised amendment to Scientific Research Permit No. 22187–02.

DATES: Written, telefaxed, or email comments must be received on or before March 7, 2022.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 22187 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 22187 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Sara Young or Shasta McClenahan, Ph.D., (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject amendment to Permit No. 22187–02 is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

On November 18, 2021, notice was published in the **Federal Register** (86 FR 64457) that a request for an amendment to a scientific research permit for research on northern elephant seals (*Mirounga angustirostris*) had been submitted by the above-named applicant. Following the close of the public comment period, the applicant made several substantive changes to the amendment request; therefore, the original request has been withdrawn from further consideration and a revised amendment request has been submitted.

Permit No. 22187–02, issued on December 13, 2021, authorizes the permit holder to conduct research to establish a catalog of known individual northern elephant seals along the California coast. Types of authorized takes include behavioral observations, measurements, bioacoustic recordings, acoustic playbacks, marking, flipper tagging, capture, and non-invasive physiological sampling. The permit holder is requesting the permit be amended to include authorization for 25 additional takes of northern elephant seals per year at two locations in California. Each animal would be handled up to three times per year. At first handling, each animal will be flipper tagged. At the second handling, each animal will be captured by hand or net, sedated and fitted with satellite transmitters, in addition to the physiological sampling already authorized. At the third handling, approximately three months later, animals would be recaptured to remove the instruments. Five additional takes are requested for animals that are captured and released because they are not appropriate candidates for the study. An additional 200 harbor seal (*Phoca vitulina*) takes and 185 elephant seal takes are requested annually for unintentional harassment during these activities. The permit holder is requesting two mortalities, an increase in the number of annual mortalities from one animal to two, but the total number of mortalities (five) allowed across the life of the permit will not change. The permit would remain valid until March 31, 2024.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: February 1, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–02420 Filed 2–3–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Highly Migratory Species Tournament Registration and Reporting

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before April 5, 2022.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0323 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Clifford Hutt, Fishery Management Specialist, NOAA Fisheries Highly Migratory Species Management Division, 1315 East-West Highway, SSMC3, Silver Spring, MD 20910; 301–427–8503; or *cliff.hutt@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection. Under the provisions of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), NOAA's National Marine Fisheries Service (NMFS) is responsible for management of the nation's marine fisheries. Existing regulations require operators of tournaments involving Atlantic highly migratory species (HMS; Atlantic swordfish, sharks, billfish, and tunas) to register four weeks in advance of the tournament. Operators must provide contact information and the tournament's date(s), location(s), and target species. Operators are required to submit an HMS tournament summary report within seven days after tournament fishing has ended. Most of the catch data in the summary report is routinely collected in the course of regular tournament operations. NMFS uses the data to estimate the total annual catch of HMS and the impact of tournament operations in relation to other types of fishing activities. In addition, HMS tournament registration provides a method for tournament operators to request educational and

regulatory outreach materials from NMFS. No changes to the reporting requirements are being made at this time.

II. Method of Collection

Operators have the choice of registering and reporting online or by electronic or paper forms. Methods of submittal include online submission (registering/reporting), email of electronic forms, and mail of paper forms.

III. Data

OMB Control Number: 0648–0323.
Form Number(s): None.
Type of Review: Regular submission (extension of a current information collection).
Affected Public: Business or other for-profit organizations; Not-for-profit institutions.
Estimated Number of Respondents: 300.
Estimated Time per Response: Tournament registration, 2 minutes; tournament summary report, 20 minutes.
Estimated Total Annual Burden Hours: 110.
Estimated Total Annual Cost to Public: $34.80 in recordkeeping/reporting costs.
Respondent's Obligation: Mandatory.
Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), and the Atlantic Tunas Convention Act of 1975 (16 U.S.C. 971 *et seq.*)

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–02394 Filed 2–3–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

NTIA IIJA Broadband Grant Program Webinars

AGENCY: National Telecommunications and Information Administration, Department of Commerce.

ACTION: Notice of open meetings.

SUMMARY: The National Telecommunications and Information Administration (NTIA) will host a pre-Notice of Funding Opportunity (NOFO) technical assistance webinar series in March–May 2022 in connection with the five new broadband grant programs authorized and funded by the Infrastructure Investment and Jobs Act (IIJA): The Broadband Equity, Access, and Deployment Program; the Enabling Middle Mile Broadband Infrastructure Program; and the Digital Equity Act Programs, which include the State Digital Equity Planning Grant Program, State Digital Equity Capacity Grant Program, and Digital Equity Competitive Grant Program. These pre-NOFO technical assistance webinars are designed to help prospective applicants understand NTIA's IIJA broadband grant programs and to assist applicants to prepare high quality grant applications.

DATES: NTIA will hold these webinars based on the following schedule:

1. IIJA Broadband Programs Pre-NOFO Technical Assistance Webinar #1: Wednesday, March 9, 2022, from 2:30–4:00 p.m. Eastern Time (ET);

2. IIJA Broadband Programs Pre-NOFO Technical Assistance Webinar #2: Wednesday, March 23, 2022, from 2:30–4:00 p.m. ET;

3. IIJA Broadband Programs Pre-NOFO Technical Assistance Webinar #3: Wednesday, April 6, 2022, from 2:30–4:00 p.m. ET;

4. IIJA Broadband Programs Pre-NOFO Technical Assistance Webinar #4: Wednesday, April 27, 2022, from 2:30–4:00 p.m. ET; and

5. IIJA Broadband Programs Pre-NOFO Technical Assistance Webinar #5: Wednesday, May 11, 2022, from 2:30–4:00 p.m. ET.

ADDRESSES: These webinars will be hosted via NTIA's virtual platform and conducted as a live webinars. NTIA will post the registration information on its BroadbandUSA website at *https://broadbandusa.ntia.doc.gov/events/latest-events.*

FOR FURTHER INFORMATION CONTACT: Maci Morin, National Telecommunications and Information Administration, U.S. Department of Commerce, Room 4872, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2048; email: *BroadbandForAll@ntia.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002; email *press@ntia.gov.*

SUPPLEMENTARY INFORMATION: The Infrastructure Investment and Jobs Act (Pub. L. 117–58) authorized and funded five new broadband grant programs to be administered by NTIA: The Broadband Equity, Access, and Deployment Program; the Enabling Middle Mile Broadband Infrastructure Program; and the Digital Equity Act Programs, which include the State Digital Equity Planning Grant Program, State Digital Equity Capacity Grant Program, and Digital Equity Competitive Grant Program. The Broadband Equity, Access, and Deployment Program is a $42.45 billion formula-based program to states, territories, and the District of Columbia for qualifying broadband deployment, mapping, and adoption project. The Enabling Middle Mile Broadband Infrastructure Program is a competitive $1 billion grant program for the construction, improvement or acquisition of middle-mile infrastructure. The Digital Equity Act Programs—which includes the State Digital Equity Planning Grant Program, State Digital Equity Capacity Grant Program, and the Digital Equity Competitive Grant Program—allocate $2.75 billion to promote digital inclusion and equity for communities that lack the skills, technologies, and support needed to take advantage of broadband connections.

These webinars are subject to change. Session time changes will be posted on the BroadbandUSA website at *https://broadbandusa.ntia.doc.gov/events/latest-events.* Any webinar cancellations will also be posted on the same website. Any date change to a scheduled webinar will be provided in a notice in the **Federal Register**.

The presentation recording, and transcript of each webinar will be posted on the BroadbandUSA website at *https://broadbandusa.ntia.doc.gov/* and NTIA's YouTube channel at: *https://www.youtube.com/ntiagov* within seven (7) days following the live session.

The public is invited to participate in these webinars. Pre-registration is required as space is limited to the first 1,000 participants. NTIA asks each registrant to provide their first and last name, city, state, zip code, job title, organization, and email address for registration purposes. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify the NTIA contact listed above at least ten (10) business days before the session. General questions and comments are welcome via email to *BroadbandForAll@ntia.gov.*

Dated: February 1, 2022.

Kathy Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2022–02354 Filed 2–3–22; 8:45 am]

BILLING CODE 3510–60–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add product(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) previously furnished by such agencies.

DATES: Comments must be received on or before: March 06, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product(s)

NSN(s)—Product Name(s): 7520–00–NIB–2491—Pen, All-Weather, Cord Loop, Black Ink, 1mm point
Designated Source of Supply: Alphapointe, Kansas City, MO
Contracting Activity: FEDERAL ACQUISITION SERVICE, GSA/FAS ADMIN SVCS ACQUISITION BR(2
Distribution: A-List
Mandatory for: Total Government Requirement

NSN(s)—Product Name(s):
MR 10831—Container, Carrot and Dip To Go, Includes Shipper 20831
MR 10816—Marvel Toys, Includes Shipper 20816
MR 10819—Celery & Dip to Go, Includes Shipper 20819
Designated Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Contracting Activity: Military Resale-Defense Commissary Agency
Distribution: C-List
Mandatory for: The requirements of military commissaries and exchanges in accordance with the 41 CFR 51–6.4

NSN(s)—Product Name(s): 8530–00–NIB–2490—Kit, Personal Sanitizing
Designated Source of Supply: Blind Industries & Services of Maryland, Baltimore, MD
Contracting Activity: FEDERAL ACQUISITION SERVICE, GSA/FSS GREATER SOUTHWEST ACQUISITI
Distribution: A-List
Mandatory for: Total Government Requirement

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
7520–00–117–5627—Fingerprint Pad—Size #1, 2¾″ x 4½″, Black
7510–00–526–1740—Foam Stamp Pad, Size #3, 4½″ x 7½″, Uninked
7510–00–231–6531—Felt Stamp Pad, Size #2, 3¼″ x 6¼″, Un-Inked
7510–00–526–1742—Foam Stamp Pad, Size #1, 2¾″ x 4½″, Un-Inked
7510–01–431–6517—Foam Stamp Pad, Size #1, 2¾″ x 4½″, Red
7510–01–431–6523—Felt Stamp Pad, Size #2, 3¼″ x 6¼″, Black
7510–01–431–6524—Foam Stamp Pad, Size #3, 4½″ x 7½″, Black
7510–01–431–6525—Foam Stamp Pad, Size #1, 2¾″ x 4½″, Black
7510–01–431–6526—Foam Stamp Pad, Size #3, 4½″ x 7½″, Red
7510–01–431–8625—Felt Stamp Pad, Size #2 3¼″ x 6¼″, Red
7510–00–224–7676—Felt Stamp Pad, Size #1, 2¾″ x 4¼″, Un-Inked
7510–00–526–1741—Foam Stamp Pad, Size #2, 3¼″ x 6¼″, Un-Inked
7510–01–431–6518—Felt Stamp Pad, Size #1, 2¾″ x 4¼″, Red
7510–01–431–6519—Foam Stamp Pad, Size # 2, 3¼″ x 6¼″, Red
7510–01–431–6521—Felt Stamp Pad, Size #1, 2¾″ x 4¼″, Black
7510–01–431–6522—Foam Stamp Pad, Size # 2, 3¼″ x 6¼″, Black
Designated Source of Supply: NYSARC, Inc., Cattaraugus Niagara Counties Chapter, Olean, NY
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s): 7530–00–142–9037—Roll, Teletype Paper, 8.44″ x 325″, White
Designated Source of Supply: CINCINNATI ASSOCIATION FOR THE BLIND AND VISUALLY IMPAIRED, Cincinnati, OH
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2022–02365 Filed 2–3–22; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes product(s) and service(s) from the Procurement List that were be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to and deleted from the Procurement List:* March 06, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 8/13/2021 and 9/17/2021, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
MR 3232—So Fabulous Monofiliment Brush
MR 3235—Ponytailers Girls
Designated Source of Supply: Association for Vision Rehabilitation and Employment, Inc., Binghamton, NY
Contracting Activity: Military Resale-Defense Commissary Agency

Service(s)

Service Type: Medical Transcription
Mandatory for: Veterans Affairs Medical Center, Alexandria, LA
Designated Source of Supply: Lighthouse for the Blind of Houston, Houston, TX
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, NAC

Service Type: Operations and Maintenance Services
Mandatory for: FAA, William J. Hughes Technical Center, Atlantic City International Airport, Atlantic City, NJ, Building 300, Fourth Floor, Atlantic City, NJ
Designated Source of Supply: Fedcap Rehabilitation Services, Inc., New York, NY
Contracting Activity: FEDERAL AVIATION ADMINISTRATION, DEPT OF TRANS/FEDERAL AVIATION ADMIN

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2022–02366 Filed 2–3–22; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Virtual Public Meeting for the Draft Environmental Impact Statement Pearl Harbor Naval Shipyard and Intermediate Maintenance Facility Dry Dock and Waterfront Production Facility

AGENCY: Department of the Navy (DoN), Department of Defense (DoD)

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) of 1969, as implemented by the Council on Environmental Quality Regulations, the DoN has prepared and filed with the United States Environmental Protection Agency (U.S. EPA) a Draft Environmental Impact Statement (EIS) that evaluates the potential environmental effects associated with constructing and operating a graving dry dock (DD) and waterfront production facility (WPF) at the Pearl Harbor Naval Shipyard and Intermediate Maintenance Facility (PHNSY & IMF) at Joint Base Pearl Harbor-Hickam (JBPHH), Oahu, Hawaii. A graving dry dock is a narrow basin constructed near the shoreline that can be flooded to allow watercraft to be floated in, then drained to allow the watercraft to come to rest on a dry platform. Dry docks are used for the maintenance and repair of ships, boats, submarines, and other watercraft. A WPF is a facility situated at the waterfront that is used to support maintenance of these vessels.

DATES: With the filing of the Draft EIS, the DoN is initiating a 45-day public comment period beginning on February 4, 2022, and extending through March 21, 2022. Comments submitted during the public comment period will become part of the public record, and substantive comments will be considered in the Final EIS. All comments must be postmarked or received electronically by 11:59 p.m. Hawaii Standard Time (HST) on March 21, 2022, for consideration in the Final EIS.

Due to current Federal and State guidance on social distancing in response to the COVID–19 pandemic, the DoN is providing virtual and web-based opportunities for the public to learn about the proposed action and action alternatives, and provide comments on the Draft EIS. The virtual and web-based opportunities are:

1. *Virtual Open House:* A Virtual Open House will be available at *https://www.pearlharbordrydockeis.org* from February 4, 2022, to March 21, 2022.

2. *Project Website:* The Project website is available at *https://www.pearlharbordrydockeis.org* throughout the EIS preparation. The Project website provides information on the proposed action, NEPA process, and schedule, and includes a document library. The public can use this website to submit comments on the Draft EIS electronically between February 4, 2022, and March 21, 2022.

3. *Virtual Public Meeting:* February 24, 2022, 4:30–6:30 p.m. HST. There are two options to access the meeting:

a. *Go to Zoom.us/join or join by phone at:* 669–900–6833; Meeting ID: 881 8171 0022.

b. *Visit the Project Website at: https://www.pearlharbordrydockeis.org* to access the Virtual Public Meeting link and phone number.

Concurrent with the NEPA public involvement process, the DoN is conducting National Historic Preservation Act Section 106 consultations regarding potential effects of the Proposed Action on historic properties. Historic properties include districts, sites, buildings, structures, or objects listed or eligible for listing in the National Register of Historic Places. The public will have the opportunity to participate in the Section 106 process by reviewing the Draft EIS and providing comments using one of the various virtual and web-based platforms identified above.

ADDRESSES: Written comments on the Draft EIS or the project's potential to affect historic properties pursuant to Section 106 of the National Historic Preservation Act may be mailed to Naval Facilities Engineering Systems Command, Attention: PHNSY & IMF DD/WPF EIS Project Manager, 258 Makalapa Drive, Suite 100, Joint Base Pearl Harbor-Hickam, HI 96860, or submitted electronically via the project website at *https://www.pearlharbordrydockeis.org.*

FOR FURTHER INFORMATION CONTACT: Andréa M. Von Burg Hall, DON PHNSY & IMF DD/WPF EIS Project Manager, at *andrea.vonburg-hall@navy.mil,* or 808–472–1425, or 258 Makalapa Drive, Suite 100, Joint Base Pearl Harbor-Hickam, HI 96860.

SUPPLEMENTARY INFORMATION: A Notice of Intent to prepare this EIS was published in the **Federal Register** on September 15, 2020 (**Federal Register** (FR) Doc 2020–19961) with a correction on September 18, 2020. The DoN's coaction proponents for this EIS are JBPHH and Naval Facilities Engineering Systems Command Program Management Office 555. The U.S. Army Corps of Engineers, Honolulu District; U.S. EPA, Region 9; and the National Marine Fisheries Service, Pacific Islands Regional Office are cooperating agencies.

PHNSY & IMF's mission is to repair, maintain, and modernize DoN fast-attack submarines and surface ships. The purpose of the proposed action is to provide appropriate dry dock capability at PHNSY & IMF no later than January 2028 to meet submarine depot maintenance mission requirements, as well as build and operate a properly sized and configured WPF to enable efficient submarine maintenance. The proposed action is needed because the existing DD3 at PHNSY & IMF does not have the necessary length or floor strength to accommodate current and future class fast-attack submarines. Additionally, an appropriately sized and adjacent WPF is needed to reduce lost operational days by increasing collaboration and efficiency among the workforce. The culmination of a replacement DD and new WPF will ensure that the Navy achieves necessary efficiencies and is capable of fulfilling scheduled maintenance requirements. The mission need date of January 2028 is driven by current projected Fleet maintenance schedules.

The DoN is considering four action alternatives that meet the purpose of and need for the proposed action, as well as a no action alternative. Under the No Action Alternative, Alternative 1, there would be no change from the status quo. Action alternatives are differentiated by the location of the WPF relative to a new dry dock (east or west), whether the WPF serves only that dry dock (single support concept) or has capability to serve more than one dry dock (multiple support concept), and whether the dry dock is covered or uncovered.

In the EIS, the DoN analyzes potential environmental impacts of the different alternatives. Additionally, the DoN will conduct all coordination and consultation activities required by the National Historic Preservation Act, the Endangered Species Act, the Magnuson-Stevens Fishery Conservation and Management Act, the Clean Water Act, and other laws and regulations determined to be applicable to the project. The DoN will implement mitigation and monitoring measures to avoid or reduce environmental impacts, as determined in cooperation with the appropriate regulatory agencies and consulting parties.

The DoN distributed the Draft EIS to federal agencies and Native Hawaiian Organizations with which the DoN is consulting and to other stakeholders. The DoN provided press releases to the local newspapers and distributed letters and postcards to stakeholders, Native Hawaiian Organizations, and other interested parties. Copies of the Draft EIS are available for public review at the following public libraries: 1. Hawaii State Public Library and 2. Salt Lake-Moanalua Public Library. The Draft EIS is also available for electronic viewing or download at *https://www.pearlharbordrydockeis.org.*

Dated: January 28, 2022.

J.M. Pike,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2022–02168 Filed 2–3–22; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Personnel Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children With Disabilities

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2022 for Personnel Development to Improve Services and Results for Children with Disabilities—Personnel Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities, Assistance Listing Number 84.325K. This notice relates to the approved information collection under OMB control number 1820–0028.

DATES:

Applications Available: February 4, 2022.

Deadline for Transmittal of Applications: April 15, 2022.

Deadline for Intergovernmental Review: June 14, 2022.

Pre-Application Webinar Information: No later than February 9, 2022, the Office of Special Education and Rehabilitative Services (OSERS) will post details on pre-recorded informational webinars designed to provide technical assistance to interested applicants. Links to the webinars may be found at *www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 27, 2021 (86 FR 73264) and available at *www.federalregister.gov/d/2021-27979.* Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov* a Data Universal Numbering System (DUNS) number to the implementation of the Unique Entity Identifier (UEI). More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

FOR FURTHER INFORMATION CONTACT:

For Absolute Priority 1 Focus Area A: Sunyoung Ahn, U.S. Department of Education, 400 Maryland Avenue SW, Room 5012A, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–6460. Email: *Sunyoung.Ahn@ed.gov.*

For Absolute Priority 1 Focus Area B: Carlene Reid, U.S. Department of Education, 400 Maryland Avenue SW, Room 5038A, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–6139. Email: *Carlene.Reid@ed.gov.*

For Absolute Priority 2: Tracie Dickson, U.S. Department of Education, 400 Maryland Avenue SW, Room 5176, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–7844. Email: *Tracie.Dickson@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of this program are to (1) help address State-identified needs for personnel preparation in special education, early intervention, related services, and regular education to work with children,

including infants, toddlers, and youth with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research, to be successful in serving those children.

Priorities: This competition includes two absolute priorities. In accordance with 34 CFR 75.105(b)(2)(v), Absolute Priority 1 and Absolute Priority 2 are from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1462 and 1481)).

Absolute Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet Absolute Priority 1 or Absolute Priority 2. The Department may fund out of rank order high-quality applications to ensure that awards are evenly funded under each absolute priority. Applicants may apply under both absolute priorities but must submit two separate applications. Applicants must clearly identify if the proposed project addresses Absolute Priority 1 or Absolute Priority 2.

These priorities are:

Absolute Priority 1: Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities who have High-Intensity Needs.

Background:

The purpose of this priority is to increase the number and improve the quality of personnel who are fully credentialed to serve children, including infants, toddlers, and youth with disabilities, who have high-intensity needs.[1] Under this priority, the Department will fund high-quality interdisciplinary[2] projects that prepare special education, early intervention, and related services[3] personnel at the master's degree, educational specialist degree, or clinical doctoral degree levels for professional practice in a variety of education settings, including natural environments (the home and community settings in which children with and without disabilities participate), early learning programs, classrooms, schools, and distance learning environments. The competition will also prepare personnel who have the knowledge and skills to support each child with a disability who has high-intensity needs, in meeting high expectations and to partner with other providers, families, and administrators in meaningful and effective collaborations.

State demand for fully credentialed special education, early intervention, and related services personnel to serve children, including infants, toddlers, and youth, with disabilities exceeds the available supply, particularly in high-need schools[4] (Boe et al., 2013). These shortages can negatively affect the quality of services provided to children, including infants, toddlers, and youth, with disabilities and their families (Boe et al., 2013). These shortages limit the field's ability to ensure that each child has the opportunity to meet challenging objectives and receive an education that addresses individualized needs and is both meaningful and appropriately ambitious, which is essential for preparing them for the future.

The need for personnel with the knowledge and skills to serve children with disabilities, including infants, toddlers, and youth, who have high-intensity needs is even greater because specialized or advanced preparation is required to collaboratively design and deliver evidence-based[5] instruction and intensive individualized intervention(s) in person and through distance learning technologies in natural environments, classrooms, and schools that address the needs of these individuals (Boe et al., 2013; Browder et al., 2014; McLeskey & Brownell, 2015).

Although children with disabilities, including infants, toddlers, and youth, who have high-intensity needs may require the combined expertise of numerous professionals (including special education, early intervention, and related services providers), it is often difficult for personnel from varied professional backgrounds to work together because they lack shared information, understanding, and experience. Personnel also need leadership skills to strengthen professional practice and cultural and linguistic competencies to effectively deliver services and education for children with disabilities who have high-intensity needs, including those who are racially and ethnically diverse.

Interdisciplinary approaches to personnel preparation provide scholars with experience working and learning in team environments similar to those in which they are likely to work once employed (Smith, 2010). That is, when providing early intervention or special education services under IDEA, personnel serving children with disabilities, including infants, toddlers, and youth, work on interdisciplinary teams with parents, general and special education teachers, early interventionists, and related service providers with the expertise to design, implement, and evaluate instruction, intervention plans, individualized family service plans, and individualized education programs based on the unique learning and developmental needs of each child. To enable personnel to provide efficient, high-quality, integrated, and equitable services, both in person and through distance learning technologies, personnel preparation programs need to embed content,

[1] For the purposes of this priority, ''high-intensity needs'' refers to a complex array of disabilities (*e.g.,* multiple disabilities, significant cognitive disabilities, significant physical disabilities, significant sensory disabilities, significant autism, significant emotional disabilities, or significant learning disabilities, including dyslexia) or the needs of children with these disabilities requiring intensive, individualized intervention(s) (*i.e.,* that are specifically designed to address persistent learning or behavior difficulties, implemented with greater frequency and for an extended duration than is commonly available in a typical classroom or early intervention setting, or which require personnel to have knowledge and skills in identifying and implementing multiple evidence-based interventions).

[2] For the purposes of this priority, ''interdisciplinary'' refers to preparing scholars from two or more graduate degree programs in special education or early intervention and one or more related services through shared coursework, group assignments, and extensive and coordinated field or clinical experiences. Different graduate degree programs across more than one institution of higher education may partner to develop an interdisciplinary project.

For the purpose of this priority, ''interdisciplinary'' does not include: (a) Individual scholars who receive two or more graduate degrees; (b) one graduate degree program that prepares scholars with different areas of focus; (c) one graduate degree program that offers interdisciplinary content but does not prepare scholars from two or more degree programs together; or (d) one graduate degree program in special education, early intervention, and related services partnering with a graduate degree program other than special education, early intervention, or related services. Programs in which scholars receive only a certificate or endorsement without a graduate degree are not eligible.

[3] For the purposes of this priority, ''related services'' includes the following: Speech-language pathology and audiology services; interpreting services; psychological services; applied behavior analysis; physical therapy and occupational therapy; recreation, including therapeutic recreation; social work services; counseling services, including rehabilitation counseling; and orientation and mobility services.

[4] For the purposes of this priority, ''high-need school'' refers to a public elementary or secondary school that is a ''high-need local educational agency (LEA),'' ''high-poverty,'' ''implementing a comprehensive support and improvement plan,'' or ''implementing a targeted support and improvement plan'' as defined in footnotes 9, 10, 11, and 12, respectively.

[5] For the purposes of this priority, ''evidence-based'' means, at a minimum, evidence that demonstrates a rationale (as defined in 34 CFR 77.1), where a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

practices, and extensive field or clinical experiences into preservice training that is culturally and linguistically responsive and aligned with an interdisciplinary team-based approach to effectively meet the needs of children with high-intensity needs and their families in ways that are culturally and linguistically responsive. This priority aims to fund interdisciplinary projects that will provide such preparation.

Priority:

The purpose of this priority is to increase the number and improve the quality of personnel who are fully credentialed to serve children, including infants and toddlers, and youth with disabilities, who have high-intensity needs—especially in areas of chronic personnel shortage. The priority will fund high-quality interdisciplinary projects that prepare special education, early intervention, and related services personnel at the master's degree, educational specialist degree, or clinical doctoral degree levels for professional practice in natural environments, early learning programs, classrooms, school settings, and in distance learning environments serving children, including infants and toddlers, and youth with disabilities.

Specifically, an applicant must propose an interdisciplinary project supporting scholars [6] from two or more graduate degree programs in special education or early intervention and one or more related services.

An interdisciplinary project is a project that delivers core content through shared coursework, group assignments, and extensive and coordinated field and clinical experiences as part of two or more master's degree, educational specialist degree, or clinical doctoral degree programs for scholars. Not all requirements (*e.g.,* courses and field or clinical experiences) of each participating graduate degree program must be shared across all degree programs participating in the interdisciplinary project, but the interdisciplinary project must: (a) Identify the competencies needed to promote high expectations and address the individualized needs of children with disabilities who have high-intensity needs using an interdisciplinary approach to service delivery; (b) outline how the project will build capacity in those areas through shared coursework, group assignments, and extensive and coordinated field or clinical experiences for scholars supported by the proposed project; and (c) identify the aspects of each graduate degree program that are shared across all participating degree programs and those that remain unique to each.

Projects may include individuals who are not funded as scholars, but are in degree programs (*e.g.,* general education, early childhood education, administration) that are cooperating with the applicant's proposed interdisciplinary project. These individuals may participate in the shared coursework, group assignments, extensive and coordinated field or clinical experiences, and other opportunities required of scholars' program of study (*e.g.,* speaker series, monthly seminars) if doing so does not diminish the benefit for project-funded scholars (*e.g.,* by reducing funds available for scholar support or limiting opportunities for scholars to participate in project activities).

Personnel preparation degree programs that prepare all scholars to be dually certified can qualify under this priority by partnering with at least one additional graduate degree program in related services.

Personnel preparation programs that prepare individuals to be educational interpreters for the deaf at the bachelor's degree level can qualify under this priority and are exempted from (a) the interdisciplinary requirement and (b) the requirement for two or more graduate degree programs. All other priority requirements specified for graduate programs will apply to the bachelor's program. While interdisciplinary projects are not required for educational interpreters, they are encouraged.

Focus Areas:

Within this absolute priority, the Secretary intends to support interdisciplinary projects under the following two focus areas: (A) Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities who have High-Intensity Needs; and (B) Preparing Personnel to Serve School-Age Children with Disabilities who have High-Intensity Needs.

Applicants must identify the specific focus area (*i.e.,* A or B) under which they are applying as part of the competition title on the application cover sheet (SF 424, line 12). Applicants may not submit the same proposal under more than one focus area. Applicants may submit different proposals in different focus areas.

Note: OSEP may fund out of rank order high-quality applications to ensure that projects are funded across both Focus Area A and Focus Area B.

Focus Area A: Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities who have High-Intensity Needs. This focus area is for interdisciplinary projects that deliver core content through shared coursework, group assignments, and extensive and coordinated field or clinical experiences for scholars across two or more graduate degree programs in early intervention or early childhood special education and one or more related services for infants, toddlers, and preschool-age children with disabilities or developmental delays who have high-intensity needs.

Early intervention personnel are those who are prepared to provide services to infants and toddlers with disabilities ages birth to three, and early childhood personnel are those who are prepared to provide services to children with disabilities ages three through five (and in States where the age range is other than ages three through five, we defer to the State's certification for early childhood special education). In States where certification in early intervention is combined with certification in early childhood special education, applicants may propose a combined early intervention and early childhood special education personnel preparation project under this focus area.

Focus Area B: Preparing Personnel to Serve School-Age Children with Disabilities who have High-Intensity Needs. This focus area is for interdisciplinary projects that deliver core content through shared coursework, group assignments, and extensive and coordinated field or clinical experiences to scholars across two or more graduate degree programs in special education and one or more related services for school-age children with disabilities who have high-intensity needs.

Focus Areas A and B:

[6] For the purposes of this priority, ''scholar'' is limited to an individual who: (a) Is pursuing a master's, educational specialist degree, or clinical doctoral graduate degree in special education, early intervention, or related services (as defined in this notice); (b) receives scholarship assistance as authorized under section 662 of IDEA (34 CFR 304.3(g)); (c) will be eligible for a license, endorsement, or certification from a State or national credentialing authority following completion of the graduate degree program identified in the application; and (d) will be able to be employed in a position that serves children with disabilities for a minimum of 51 percent of their time or case load. See *https://pdp.ed.gov/OSEP/Home/Regulation* for more information.

Scholars from each graduate degree program participating in the proposed interdisciplinary project must receive scholar support and be eligible to fulfill service obligation requirements following graduate degree program completion. Scholars from each graduate degree program participating in this project must complete the requirements of their unique graduate degree program and receive different graduate degrees. Individuals pursuing degrees in general education or early childhood education do not qualify as ''scholars'' eligible for scholarship assistance.

Applicants may use up to the first 12 months of the performance period and up to $100,000 of the first budget period for planning without enrolling scholars. Applicants must clearly provide sufficient justification for requesting program planning time and include the goals, objectives, and intended outcomes of program planning in year one, a description of the proposed strategies and activities to be supported, and a timeline for the work. A description of the proposed strategies may include activities such as—

(1) Outlining or updating coursework, group assignments, or extensive and coordinated field or clinical experiences needed to support culturally and linguistically responsive, interdisciplinary preparation for special education, early intervention, or related services personnel serving children with disabilities who have high-intensity needs;

(2) Building capacity (*e.g.,* hiring of a field supervisor, providing professional development for field supervisors, and training for faculty);

(3) Purchasing needed resources (*e.g.,* additional teaching supplies or specialized equipment to enhance instruction); or

(4) Establishing relationships with programs or schools, including those with racially and ethnically diverse populations, to serve as sites for field or clinical experiences needed to support delivery of the proposed interdisciplinary project.

Additional Federal funds may be requested for scholar support and other grant activities occurring in year one of the project, provided that the total request for year one does not exceed the maximum award available for one budget period of 12 months (*i.e.,* $250,000).

Note: Applicants proposing projects to develop, expand, or add a new area of emphasis to special education, early intervention, or related services programs must provide, in their applications, information on how these new areas will be sustained in their programs once Federal funding ends.

Note: Project periods under this priority may be up to 60 months. Projects should be designed to ensure that all proposed scholars successfully complete the program within 60 months of the start of the project. The Secretary may reduce continuation awards for any project in which scholars are not on track to complete the program by the end of that period.

To be considered for funding under this absolute priority, all program applicants must meet the requirements contained in this priority.

To meet the requirements of this priority an applicant must—

(a) Demonstrate, in the narrative section of the application under ''Significance,'' how—

(1) The project addresses national, State, regional, or district shortages of personnel who are fully qualified to serve children with disabilities who have high-intensity needs in the focus area under which the project is applying. To address this requirement, the applicant must—

(i) Present data for all scholars in the program and provide disaggregated data for scholars of color that reflects the quality of each special education, early intervention, or related services personnel preparation degree program participating in the project, in areas such as: The average amount of time it takes for scholars to complete the program; the percentage of program graduates who receive a license, endorsement, or certification related to special education, related services, or early intervention services; the percentage of program graduates finding employment related to their preparation after graduation; the effectiveness of program graduates in providing special education, early intervention, or related services, which could include data on the learning and developmental outcomes of children with disabilities they serve; the percentage of program graduates who maintain employment for two or more years in the area for which they were prepared; and the percentage of employers who rate the preparation of scholars who complete their degree program as adequate or higher; and

(ii) If available for the degree programs participating in the proposed project, present data on the quality of their interdisciplinary approaches to the preparation of special education, early intervention, or related services personnel; and

Note: Data on the quality of a personnel preparation program should be no older than five years prior to the start date of the project proposed in the application. When reporting percentages, the denominator (*i.e.,* total number of scholars or program graduates) must be provided.

(2) The project will increase the number of personnel who demonstrate the competencies [7] needed to—

(i) Promote high expectations and improve outcomes for children with disabilities;

(ii) Differentiate curriculum and instruction;

(iii) Provide intensive, evidence-based individualized instruction and intervention(s);

(iv) Provide culturally and linguistically responsive instruction and services;

(v) Provide instruction or intervention(s) in person and through distance learning technologies;

(vi) Collaborate with diverse stakeholders, including those from racially and ethnically diverse backgrounds, using an interdisciplinary team-based approach to address the individualized needs of children with disabilities who have high-intensity needs, ages birth through 21, and designed to achieve improvements in learning or developmental outcomes (*e.g.,* academic, social, emotional, behavioral), and support the successful transition from early childhood to elementary, elementary to secondary, or transition to postsecondary education and the workforce; and

(vii) Exercise leadership to improve professional practice and services and education for children with disabilities who have high-intensity needs.

To address this requirement, the applicant must—

(A) Identify the competencies that special education, early intervention, or related services personnel need to—

(*1*) Promote high expectations and improve outcomes for children with disabilities;

(*2*) Differentiate curriculum and instruction;

(*3*) Provide intensive, evidence-based individualized instruction and intervention(s);

(*4*) Provide culturally and linguistically responsive instruction and services;

(*5*) Provide instruction or intervention(s) in person and through distance learning technologies;

(*6*) Collaborate with parents, families, and diverse stakeholders, including those who are from racially and ethnically diverse backgrounds, using an interdisciplinary team-based approach designed to improve learning and developmental outcomes; ensure access to and progress in academic achievement standards or alternate academic achievement standards, as appropriate; lead to successful

[7] For the purposes of this priority, ''competencies'' means what a person knows and can do—the knowledge, skills, and dispositions necessary to effectively function in a role (National Professional Development Center on Inclusion, 2011). These competencies should ensure that personnel are able to use challenging academic standards, child achievement and functional standards, and assessments to improve instructional practices, services, learning and developmental outcomes (*e.g.,* academic, social, emotional, behavioral), and college- and career-readiness of children with disabilities.

transition to college and career for children with disabilities, including children with disabilities who have high-intensity needs; and maximize the use of effective technology, including assistive technology, to deliver instruction, interventions, and services; and

(7) Exercise leadership to improve professional practice and services and education for children with disabilities who have high-intensity needs and their families;

(B) Identify the competencies needed by members of interdisciplinary teams to promote high expectations and improve early childhood, educational, and employment outcomes for children with disabilities who have high-intensity needs;

(C) Identify the competencies that personnel need to support inclusion of children with disabilities who have high-intensity needs in the least restrictive and natural environments to the maximum extent appropriate by intentionally promoting high expectations and participation in learning and social activities to foster development, learning, academic achievement, friendships with peers, and sense of belonging;

(D) Identify how scholars will be prepared to develop, implement, and evaluate evidence-based instruction and evidence-based interventions delivered in person and through distance learning technologies that improve outcomes for children with disabilities who have high-intensity needs in a variety of settings (*e.g.,* natural environments; public schools, including charter schools; private schools; and other nonpublic education settings, including home education); and

(E) Provide a conceptual framework for the proposed interdisciplinary personnel preparation project, including any empirical support for project activities designed to promote the acquisition of the identified competencies (see paragraph (a)(2) of the requirements for this priority) needed by special education, early intervention, or related services personnel, and how these competencies relate to the proposed project.

(b) Demonstrate, in the narrative section of the application under ''Quality of project services,'' how the project—

(1) Will conduct its planning activities, if the applicant will use any of the allowable first 12 months of the project period for planning;

(2) Will recruit and retain high-quality scholars into each of the graduate degree programs participating in the project and ensure equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe—

(i) Criteria the applicant will use to identify high-quality applicants for admission into each of the graduate degree programs participating in the project;

(ii) Recruitment strategies the applicant will use to attract high-quality applicants, including specific recruitment strategies targeting high-quality applicants from traditionally underrepresented groups, including underrepresented people of color and individuals with disabilities; and

(iii) The approach, including mentoring, monitoring, and accommodations, the applicant will use to support scholars to complete their respective degree programs;

(3) Reflects current evidence-based practices, including practices in the areas of literacy and numeracy development, assessment, behavior, instructional practices, distance learning technologies and pedagogy, and inclusive strategies, as appropriate, and is designed to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how the project will—

(i) Incorporate current evidence-based practices (including relevant research citations) that improve outcomes for children with disabilities who have high-intensity needs into (a) the required coursework and extensive field or clinical experiences for each graduate degree program participating in the project; and (b) the shared coursework, group assignments, and extensive and coordinated field or clinical experiences required for the interdisciplinary portions of the project; and

(ii) Use evidence-based professional development practices for adult learners to instruct scholars through both in-person and online courses and field or clinical experiences;

(4) Is of sufficient quality, intensity, and duration to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how—

(i) The components of (a) each graduate degree program participating in the project; and (b) the shared coursework, group assignments, and extensive and coordinated field or clinical experiences required for the interdisciplinary portions of the proposed project will support scholars' acquisition and enhancement of the identified competencies;

(ii) The components of (a) each graduate degree program participating in the project; and (b) the shared coursework, group assignments, and extensive and coordinated field or clinical experiences required for the interdisciplinary portions of the proposed project will be integrated to allow scholars, in collaboration with other team members, to use their knowledge and skills in designing, implementing, and evaluating practices supported by evidence to address the learning and developmental needs of children with disabilities who have high-intensity needs;

(iii) Scholars will be provided with ongoing guidance and feedback during training; and

(iv) The proposed project will provide ongoing induction opportunities and mentoring support to graduates of each graduate degree program participating in the project;

(5) Will engage in meaningful and effective collaboration with appropriate partners representing diverse stakeholders, including—

(i) High-need schools, which may include high-need local educational agencies (LEAs),[8] high-poverty schools,[9] schools identified for comprehensive support and improvement,[10] and schools implementing a targeted support and improvement plan [11] for children with disabilities; early childhood and early intervention

[8] For the purposes of this priority, ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children are from families with incomes below the poverty line.

[9] For the purposes of this priority, ''high-poverty school'' means a school in which at least 50 percent of students are from low-income families as determined using one of the measures of poverty specified under section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school under this definition is determined on the basis of the most currently available data.

[10] For the purposes of this priority, ''school implementing a comprehensive support and improvement plan'' means a school identified for comprehensive support and improvement by a State under section 1111(c)(4)(D) of the ESEA that includes (a) not less than the lowest performing 5 percent of all schools in the State receiving funds under Title I, Part A of the ESEA; (b) all public high schools in the State failing to graduate one third or more of their students; and (c) public schools in the State described under section 1111(d)(3)(A)(i)(II) of the ESEA.

[11] For the purposes of this priority, ''school implementing a targeted support and improvement plan'' means a school identified for targeted support and improvement by a State that has developed and is implementing a school-level targeted support and improvement plan to improve student outcomes based on the indicators in the statewide accountability system as defined in section 1111(d)(2) of the ESEA.

programs located within the geographic boundaries of a high-need LEA; and early childhood and early intervention programs located within the geographical boundaries of an LEA serving the highest percentage of schools identified for comprehensive support and improvement or implementing targeted support and improvement plans in the State. The purpose of these partnerships is to provide extensive field or clinical practice for scholars aimed at developing the identified competencies as members of interdisciplinary teams; and

(ii) Other personnel preparation programs on campus or at partnering universities for the purpose of sharing resources, supporting program development and delivery, and addressing personnel shortages;

(6) Will use technology, as appropriate, to promote scholar learning and professional practice, enhance the efficiency of the project, collaborate with partners, and facilitate ongoing mentoring and support for scholars;

(7) Will ensure that scholars understand how to use technology to support children's in-person and distance learning and children's use of educational and assistive technology; and

(8) Will align with and use resources, as appropriate, available through technical assistance centers, which may include centers funded by the Department;

Note: Use the ''Find a Center or Grant'' link at *https://osepideasthatwork.org* for information about OSEP-funded technical assistance centers.

(c) Demonstrate, in the narrative section of the application under ''Quality of the project evaluation,'' how—

(1) The applicant will use comprehensive and appropriate methodologies to evaluate how well the goals or objectives of the proposed project have been met, including the project processes and outcomes;

(2) The applicant will collect, analyze, and use data related to specific and measurable goals, objectives, and outcomes of the project. To address this requirement, the applicant must describe how—

(i) Scholar competencies and other project processes and outcomes will be measured for formative evaluation purposes, including proposed instruments, data collection methods, and possible analyses; and

(ii) It will collect and analyze data on the quality of services provided by scholars who complete the graduate degree programs involved in this interdisciplinary project and are employed in the field for which they were trained, including data on the learning and developmental outcomes (*e.g.,* academic, social, emotional, behavioral, meeting college- and career-ready standards), and on growth toward these outcomes, of the children with disabilities who have high-intensity needs;

Note: Following the completion of the project period, grantees are encouraged to engage in ongoing data collection activities.

(3) The methods of evaluation will produce quantitative and qualitative data for objective performance measures that are related to the outcomes of the proposed project; and

(4) The methods of evaluation will provide performance feedback and allow for periodic assessment of progress towards meeting the project outcomes. To address this requirement, the applicant must describe how—

(i) Results of the evaluation will be used to improve the proposed project to prepare special education, early intervention, or related services personnel to provide (a) focused instruction; and (b) intensive individualized intervention(s) in an interdisciplinary team-based approach to improve outcomes of children with disabilities who have high-intensity needs; and

(ii) The grantee will report the evaluation results to OSEP in its annual and final performance reports.

(d) Demonstrate, in the narrative under ''Project Assurances'' or in the applicable appendices, that the following program requirements are met. The applicant must—

(1) Provide scholar support for participants from two or more graduate degree programs partnering in the proposed interdisciplinary personnel preparation project. Consistent with 34 CFR 304.30, each scholar must (a) receive support for no less than one academic year, and (b) be eligible to fulfill service obligation requirements following degree program completion. Funding across degree programs may be applied differently;

(2) Include in Appendix B of the application—

(i) Table(s) that summarize the required program of study for each degree program that clearly delineate the shared coursework, group assignments, and extensive and coordinated field or clinical experiences required of all project scholars to support interdisciplinary practice;

(ii) Course syllabi for all coursework in the major of each degree program and all shared courses, group assignments, and extensive coordinated field or clinical experiences required of project scholars; and

(iii) Learning outcomes for proposed coursework;

(3) Ensure that a comprehensive set of completed syllabi, including syllabi created or revised as part of a project planning year, are submitted to OSEP by the end of year one of the grant;

(4) Ensure that efforts to recruit a diverse range of scholars, including diversity of race, ethnicity, or national origin, are consistent with applicable law. For instance, grantees may engage in focused outreach and recruitment to increase the diversity of the applicant pool prior to the selection of scholars;

(5) Ensure that the project will meet all requirements in 34 CFR 304.23, particularly those related to (a) informing all scholarship recipients of their service obligation commitment and (b) disbursing scholar support. Failure by a grantee to properly meet these requirements would be a violation of the grant award that could result in sanctions, including the grantee being liable for returning any misused funds to the Department;

(6) Ensure that prior approval from the OSEP project officer will be obtained before admitting additional scholars beyond the number of scholars proposed in the application and before transferring a scholar to another OSEP-funded grant;

(7) Ensure that the project will meet the statutory requirements in section 662(e) through (h) of IDEA;

(8) Ensure that at least 65 percent of the total award over the project period (*i.e.,* up to 5 years) will be used for scholar support. Applicants proposing to use year one for program development may budget for less than 65 percent of the total requested budget over the 5 years for scholar support; such applicants must ensure that 65 percent of the total award minus funds allocated for program development will be used for scholar support;

(9) Ensure that the institution of higher education (IHE) at which scholars are enrolled in the program will not require those scholars to work (*e.g.,* as graduate assistants) as a condition of receiving support (*e.g.,* tuition, stipends) from the proposed project, unless the work is specifically related to the acquisition of scholars' competencies or the requirements for completion of their personnel preparation program. This prohibition on work as a condition of receiving support does not apply to the service obligation requirements in section 662(h) of IDEA;

(10) Ensure that scholar support costs (*e.g.,* tuition, stipends) are scholarship assistance and not financial assistance based on the condition that the scholar works for the grantee (*e.g.,* as graduate assistants);

(11) Ensure that the budget includes attendance of the project director at a three-day project directors' meeting in Washington, DC during each year of the project. The project must reallocate funds for travel to the project directors' meeting no later than the end of the third quarter of each budget period if the meeting is conducted virtually;

(12) Ensure that the project director, key personnel, and, as appropriate, scholars will actively participate in the cross-project collaboration, advanced trainings, and cross-site learning opportunities (*e.g.,* webinars, briefings) organized by OSEP. This network will be used to build capacity of participants, increase the impact of funding, and promote innovative and interdisciplinary service delivery models across projects;

(13) Ensure that if the project maintains a website, relevant information and documents are in a format that meets government or industry-recognized standards for accessibility; and

(14) Ensure that annual data will be submitted on each scholar who receives grant support (OMB Control Number 1820–0686). The primary purposes of the data collection are to track the service obligation fulfillment of scholars who receive funds from OSEP grants and to collect data for program performance measure reporting under 34 CFR 75.110. Applicants are encouraged to visit the Personnel Development Program Data Collection System (DCS) website at *https://pdp.ed.gov/osep* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant, although grantees may submit data as needed, year round. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590). Data collection includes the submission of a signed, completed Pre-Scholarship Agreement and Exit Certification for each scholar funded under an OSEP grant (see paragraph (5) of these requirements).

Absolute Priority 2: Preparation of Special Education, Early Intervention, and Related Services Personnel Attending Minority Serving Institutions (MSIs), including Historically Black Colleges and Universities (HBCUs), Hispanic Serving Institutions (HSIs), Tribal Colleges and Universities (TCUs), and Asian American and Pacific Islander Serving Institutions (AAPISIs).

Background:

The purpose of this priority is to increase the number of ethnically and racially diverse personnel who are fully credentialed to serve children, including infants, toddlers, and youth with disabilities. Under this absolute priority, the Department will fund high-quality projects within MSIs [12] that prepare special education, early intervention, and related services [13] personnel at the certification,[14] bachelor's degree, master's degree, educational specialist degree, or clinical doctoral degree levels to serve in a variety of settings, including natural environments (the home and community settings in which children with and without disabilities participate), early learning programs, child care, classrooms, schools, and distance learning.

Children of color represent a large proportion of the children receiving early intervention and special education services through IDEA. In 2019, approximately 50 percent of infants and toddlers with disabilities, ages birth through two are children of color; approximately 48 percent of preschool children with disabilities ages three through five are children of color; while approximately 54 percent of students with disabilities, ages five (in kindergarten) through 21 are children of color (U.S. Department of Education, 2020).

Despite the fact that children of color make up an increasing share of all children receiving early intervention and special education services, results from the 2017–18 National Teacher and Principal Survey show that teachers of color comprised about 20 percent of the public school teacher workforce, which is disproportionately low compared to the proportion of students of color enrolled in public schools (Taie & Goldring, 2020).

Moreover, the demographics of personnel entering the early intervention and special education fields are not aligned with the demographics of the children and families served under IDEA. OSEP's Personnel Development Program Data Collection System data reveals that scholars are more likely to be White. Specifically, the race/ethnicity of scholars obtaining a graduate degree to serve children with disabilities is 62 percent White, 14 percent Hispanic, 9 percent Black, and 3 percent Asian. Similarly, data from related services professional organizations reveal that the majority of those enrolled in related service personnel preparation programs are White with demonstrably smaller percentages of scholars of color enrolled in preservice programs (American Occupational Therapy Association, 2020; American Physical Therapy Association, 2020; American Speech-Language Hearing Association, 2021). The data clearly demonstrates that there is a substantial shortage of ethnically and racially diverse special education, early intervention, and related services providers (Sutcher, Darling-Hammond, & Carver-Thomas, 2016).

This is of concern, as research indicates that increasing the diversity of personnel can have positive impacts on all children, and this is especially true for children of color who demonstrate improved academic achievement and behavioral and social-emotional development when they are taught by teachers of color (Carver-Thomas, 2018).

To address the need for a more diverse workforce, this priority aims to fund projects at MSIs that will prepare personnel in special education, early intervention, or a related service at the certification, bachelor's degree, master's degree, educational specialist degree, or clinical doctorate degree level.

Priority:

The purpose of this priority is to increase the number of ethnically and racially diverse personnel who have the necessary knowledge and skills to become fully credentialed to serve children, including infants, toddlers, and youth, with disabilities. The priority will support high-quality projects in MSIs that prepare special education, early intervention, and related services scholars [15] at the

[12] For the purposes of this priority, ''minority serving institutions'' are institutions of higher education whose enrollment of a single minority or a combination of minorities exceeds 50 percent of the total enrollment (20 U.S.C. 1067k(3)).

[13] For the purposes of this priority, ''related services'' includes the following: speech-language pathology and audiology services; interpreting services; psychological services; applied behavior analysis; physical therapy and occupational therapy; recreation, including therapeutic recreation; social work services; counseling services, including rehabilitation counseling; and orientation and mobility services.

[14] For the purpose of this priority, ''certification'' refers to programs of study that lead to State licensure, endorsement, or certification that qualifies graduates to teach or provide services to children with disabilities. Programs of study that lead to a certificate of completion from the MSI, but do not lead to State licensure, endorsement, or certification, do not qualify.

[15] For the purposes of this priority, ''scholar'' is limited to an individual who: (a) Is pursuing a certification, bachelor's master's, educational

certification, bachelor's degree, master's degree, educational specialist degree, or clinical doctoral degree levels for professional practice in natural environments, early learning programs, classrooms, school settings, and in distance learning environments serving children, including infants, toddlers, and youth, with disabilities.

Focus Areas:

Within this absolute priority, the Secretary intends to support projects under the following two focus areas: (A) Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities; and (B) Preparing Personnel to Serve School-Age Children with Disabilities. Applicants must identify the specific focus area (*i.e.,* A or B) under which they are applying as part of the competition title on the application cover sheet (SF 424, line 12). Applicants may not submit the same proposal under more than one focus area. Applicants may submit different proposals in different focus areas. OSEP may fund out of rank order high-quality applications to ensure that projects are funded across both Focus Area A and Focus Area B.

Focus Area A: Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities.

This focus area is for projects that prepare early intervention, special education, and related services personnel who are prepared to provide services to infants and toddler with disabilities ages birth to two, and those who are prepared to provide services to children with disabilities ages three through five (and in States where the age range is other than ages three through five, we defer to the State's certification for early childhood special education). In States where certification in early intervention is combined with certification in early childhood special education, applicants may propose a combined early intervention and early childhood special education personnel preparation project under this focus area.

Focus Area B: Preparing Personnel to Serve School-Age Children with Disabilities. This focus area is for projects that prepare special education and related services personnel to work with school-age children.

Focus Areas A and B:

Applicants may use up to the first 12 months of the performance period and up to $100,000 of the first budget period for planning without enrolling scholars. Applicants must clearly provide sufficient justification for requesting program planning time and include the goals, objectives, and intended outcomes of program planning in year one, a description of the proposed strategies and activities to be supported, and a timeline for the work. A description of the proposed strategies may include activities such as—

(1) Outlining or updating coursework, assignments, or extensive and coordinated field or clinical experiences needed to support preparation for special education, early intervention, or related services personnel serving children with disabilities;

(2) Building capacity (*e.g.,* hiring of a field supervisor, providing professional development for field supervisors, and training for faculty);

(3) Purchasing needed resources (*e.g.,* additional teaching supplies or specialized equipment to enhance instruction); or

(4) Establishing relationships with programs or schools to serve as sites for field or clinical experiences needed to support delivery of the proposed project.

Additional Federal funds may be requested for scholar support and other grant activities occurring in year one of the project, provided that the total request for year one does not exceed the maximum award available for one budget period of 12 months (*i.e.,* $250,000).

Note: Applicants proposing projects to develop, expand, or add a new area of emphasis to early intervention, special education, or related services programs must provide, in their applications, information on how these new areas will be sustained in their programs once Federal funding ends.

Note: Project periods under this priority may be up to 60 months. Projects should be designed to ensure that all proposed scholars successfully complete the program within 60 months of the start of the project. The Secretary may reduce continuation awards for any project in which scholars are not on track to complete the program by the end of that period.

To be considered for funding under this absolute priority, all program applicants must meet the requirements contained in this priority.

To meet the requirements of this priority an applicant must—

(a) Demonstrate, in the narrative section of the application under ''Significance,'' how—

(1) The project addresses national, State, regional, or district shortages of personnel who are fully qualified to serve children with disabilities in the focus area under which the project is applying. To address this requirement, the applicant must—

(i) Present data for all scholars in the program and provide disaggregated data for scholars of color that reflects the quality of the special education, early intervention, or related services personnel preparation degree program participating in the project, in areas such as: The average amount of time it takes for scholars to complete the program; the percentage of program graduates who receive a license, endorsement, or certification related to special education, related services, or early intervention services; the percentage of program graduates finding employment related to their preparation after graduation; the effectiveness of program graduates in providing special education, early intervention, or related services, which could include data on the learning and developmental outcomes of children with disabilities they serve; the percentage of program graduates who maintain employment for two or more years in the area for which they were prepared; and the percentage of employers who rate the preparation of scholars who complete their degree program as adequate or higher; and

(ii) Present data on the quality of the pedagogical approach to the preparation of special education, early intervention, or related services personnel; and

Note: Data on the quality of a personnel preparation program should be no older than five years prior to the start date of the project proposed in the application. When reporting percentages, the denominator (*i.e.,* total number of scholars or program graduates) must be provided.

(2) The project will increase the number of personnel, including those from racially and ethnically diverse backgrounds, who demonstrate the competencies [16] needed to—

specialist degree, or clinical doctoral graduate degree in special education, early intervention, or related services (as defined in this notice); (b) receives scholarship assistance as authorized under section 662 of IDEA (34 CFR 304.3(g)); (c) will be eligible for a license, endorsement, or certification from a State or national credentialing authority following completion of the program of study identified in the application; and (d) will be able to be employed in a position that serves children with disabilities for a minimum of 51 percent of their time or case load. See *https://pdp.ed.gov/OSEP/Home/Regulation* for more information.

Individuals pursuing degrees in general education or early childhood education do not qualify as ''scholars'' eligible for scholarship assistance.

[16] For the purposes of this priority, ''competencies'' means what a person knows and can do—the knowledge, skills, and dispositions necessary to effectively function in a role (National Professional Development Center on Inclusion, 2011). These competencies should ensure that personnel are able to use challenging academic standards, child achievement and functional

Continued

(i) Promote high expectations and improve outcomes for children with disabilities;

(ii) Differentiate curriculum and instruction;

(iii) Provide individualized, evidence-based instruction and intervention(s);

(iv) Provide culturally and linguistically responsive instruction and services;

(v) Provide instruction or intervention(s) in person and through distance learning technologies;

(vi) Collaborate with diverse stakeholders, including those from racially and ethnically diverse backgrounds, to address the individualized needs of children with disabilities, ages birth through 21, and designed to achieve improvements in learning or developmental outcomes (*e.g.,* academic, social, emotional, behavioral), and support the successful transition from early childhood to elementary, elementary to secondary, or transition to postsecondary education and the workforce; and

(vii) Exercise leadership to improve professional practice and services and education for children with disabilities, including those from racially and ethnically diverse backgrounds. To address this requirement, the applicant must—

(A) Identify the competencies that special education, early intervention, or related services personnel need to—

(*1*) Promote high expectations and improve outcomes for children with disabilities;

(*2*) Differentiate curriculum and instruction;

(*3*) Provide individualized, evidence-based instruction and intervention(s);

(*4*) Provide culturally and linguistically responsive instruction and services;

(*5*) Provide instruction or intervention(s) in person and through distance learning technologies;

(*6*) Collaborate with parents, families, and stakeholders, including those from racially and ethnically diverse backgrounds, to improve learning and developmental outcomes; ensure access to, and progress in, academic achievement standards or alternate academic achievement standards, as appropriate; lead to successful transition to college and career for children with disabilities; and maximize the use of effective technology, including assistive technology, to deliver instruction, interventions, and services; and

(*7*) Exercise leadership to improve professional practice and services and education for children with disabilities, including those from racially and ethnically diverse backgrounds;

(B) Identify the competencies that personnel need to support inclusion of children with disabilities in the least restrictive and natural environments to the maximum extent appropriate by intentionally promoting high expectations and participation in learning and social activities to foster development, learning, academic achievement, friendships with peers, and sense of belonging;

(C) Identify how scholars will be prepared to develop, implement, and evaluate evidence-based instruction and evidence-based interventions delivered in person and through distance learning technologies that improve outcomes for children with disabilities, including those from racially and ethnically diverse backgrounds, in a variety of settings (*e.g.,* natural environments; public schools, including charter schools; private schools; and other nonpublic education settings, including home education); and

(D) Provide a conceptual framework for the proposed personnel preparation project, including any empirical support for project activities designed to promote the acquisition of the identified competencies (see paragraph (a)(2) of the requirements for this priority) needed by special education, early intervention, or related services personnel, and how these competencies relate to the proposed project;

(b) Demonstrate, in the narrative section of the application under ''Quality of project services,'' how the project—

(1) Will recruit and retain high-quality scholars into the program and ensure equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe—

(i) Criteria the applicant will use to identify high-quality applicants for admission into the programs;

(ii) Recruitment strategies the applicant will use to attract high-quality applicants, including specific recruitment strategies targeting high-quality applicants from traditionally underrepresented groups, including underrepresented people of color and individuals with disabilities; and

(iii) The approach, including necessary supports and services that improve graduation rates such as, but not limited to, culturally and linguistically responsive mentoring and counseling, explicit strategies and support for standardized test taking (*e.g.,* Praxis tests), monitoring, and accommodations, the applicant will use to support scholars to complete their program of study;

(2) Will reflect current culturally and linguistically competent evidence-based practices, including practices in the areas of early learning and development, literacy and numeracy development, assessment, behavior, instructional practices, distance learning technologies and pedagogy, and inclusive strategies, as appropriate, and is designed to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how the project will—

(i) Incorporate current culturally and linguistically competent evidence-based practices (including relevant research citations) that improve outcomes for children with disabilities into the required coursework and extensive field or clinical experiences for the program; and

(ii) Use culturally and linguistically competent evidence-based professional development practices for adult learners to instruct scholars through both in-person and online courses and field or clinical experiences;

(3) Is of sufficient quality, intensity, and duration to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how—

(i) The components of the program of study, including the coursework, assignments, and extensive and coordinated field or clinical experiences required for the proposed project, will support scholars' acquisition and enhancement of the identified competencies;

(ii) The components of the program of study will be integrated to allow scholars to use their knowledge and skills in designing, implementing, and evaluating practices supported by evidence to address the learning and developmental needs of children with disabilities;

(iii) Scholars will be provided with ongoing culturally and linguistically responsive guidance, mentoring, feedback, and other necessary supports during training; and

(iv) The proposed project will provide ongoing culturally and linguistically responsive induction opportunities and mentoring support to graduates of the project;

(4) Will engage in meaningful and effective collaboration with appropriate

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standards, and assessments to improve instructional practices, services, learning and developmental outcomes (*e.g.,* academic, social, emotional, behavioral), and college- and career-readiness of children with disabilities.

partners representing diverse stakeholders, including—

(i) High-need schools, which may include high-need LEAs,[17] high-poverty schools,[18] schools identified for comprehensive support and improvement,[19] and schools implementing a targeted support and improvement plan [20] for children with disabilities; early childhood and early intervention programs located within the geographic boundaries of a high-need LEA; and early childhood and early intervention programs located within the geographical boundaries of an LEA serving the highest percentage of schools identified for comprehensive support and improvement or implementing targeted support and improvement plans in the State. The purpose of these partnerships is to provide extensive field or clinical practice for scholars aimed at developing the identified competencies; and

(ii) Other personnel preparation programs on campus or at partnering universities for the purpose of sharing resources, supporting program development and delivery, and addressing personnel shortages;

(5) Will use technology, as appropriate, to promote scholar learning and professional practice, enhance the efficiency of the project, collaborate with partners, and facilitate ongoing culturally and linguistically responsive mentoring and support for scholars;

(6) Will ensure that scholars understand how to use technology to support children's in-person and distance learning and children's use of educational and assistive technology; and

(7) Will align with and use resources, as appropriate, available through technical assistance centers, which may include centers funded by the Department;

Note: Use the ''Find a Center or Grant'' link at *https://osepideasthatwork.org* for information about OSEP-funded technical assistance centers.

(c) Demonstrate, in the narrative section of the application under ''Quality of the project evaluation,'' how—

(1) The applicant will use comprehensive and appropriate methodologies to evaluate how well the goals or objectives of the proposed project have been met, including the project processes and outcomes;

(2) The applicant will collect, analyze, and use data related to specific and measurable goals, objectives, and outcomes of the project. To address this requirement, the applicant must describe how—

(i) Scholar competencies and other project processes and outcomes will be measured for formative evaluation purposes, including proposed instruments, data collection methods, and possible analyses; and

(ii) It will collect and analyze data on the quality of services provided by scholars who complete the degree program and are employed in the field for which they were trained, including data on the learning and developmental outcomes (*e.g.,* academic, social, emotional, behavioral, meeting college- and career-ready standards), and on growth toward these outcomes, of the children with disabilities served by the scholars;

Note: Following the completion of the project period, grantees are encouraged to engage in ongoing data collection activities.

(3) The methods of evaluation will produce quantitative and qualitative data for objective performance measures that are related to the outcomes of the proposed project; and

(4) The methods of evaluation will provide performance feedback and allow for periodic assessment of progress towards meeting the project outcomes. To address this requirement, the applicant must describe how—

(i) Results of the evaluation will be used to improve the proposed project to prepare special education, early intervention, or related services personnel to provide (a) focused instruction; and (b) individualized intervention(s) to improve outcomes of children with disabilities; and

(ii) The grantee will report the evaluation results to OSEP in its annual and final performance reports;

(d) Demonstrate, in the narrative under ''Project Assurances'' or in the applicable appendices, that the following program requirements are met. The applicant must—

(1) Provide scholar support for participants. Consistent with 34 CFR 304.30, each scholar must (a) receive support for no less than one academic year, and (b) be eligible to fulfill service obligation requirements following degree program completion. Funding across degree programs may be applied differently;

(2) Include in Appendix B of the application—

(i) Course syllabi for all coursework in the program, assignments, and extensive coordinated field or clinical experiences required of project scholars; and

(ii) Intended learning outcomes for the proposed coursework;

(3) Ensure that a comprehensive set of completed syllabi, including syllabi created or revised as part of a project planning year, are submitted to OSEP by the end of year one of the grant;

(4) Ensure that efforts to recruit a diverse range of scholars, including diversity of race, ethnicity, or national origin, are consistent with applicable law. For instance, grantees may engage in focused outreach and recruitment to increase the diversity of the applicant pool prior to the selection of scholars;

(5) Ensure that the project will meet all requirements in 34 CFR 304.23, particularly those related to (a) informing all scholarship recipients of their service obligation commitment and (b) disbursing scholar support. Failure by a grantee to properly meet these requirements would be a violation of the grant award that could result in sanctions, including the grantee being liable for returning any misused funds to the Department;

(6) Ensure that prior approval from the OSEP project officer will be obtained before admitting additional scholars beyond the number of scholars proposed in the application and before transferring a scholar to another OSEP-funded grant;

(7) Ensure that the project will meet the statutory requirements in section 662(e) through (h) of IDEA;

(8) Ensure that at least 65 percent of the total award over the project period (*i.e.,* up to 5 years) will be used for

[17] For the purposes of this priority, ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children are from families with incomes below the poverty line.

[18] For the purposes of this priority, ''high-poverty school'' means a school in which at least 50 percent of students are from low-income families as determined using one of the measures of poverty specified under section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school under this definition is determined on the basis of the most currently available data.

[19] For the purposes of this priority, ''school implementing a comprehensive support and improvement plan'' means a school identified for comprehensive support and improvement by a State under section 1111(c)(4)(D) of the ESEA that includes (a) not less than the lowest performing 5 percent of all schools in the State receiving funds under Title I, Part A of the ESEA; (b) all public high schools in the State failing to graduate one third or more of their students; and (c) public schools in the State described under section 1111(d)(3)(A)(i)(II) of the ESEA.

[20] For the purposes of this priority, ''school implementing a targeted support and improvement plan'' means a school identified for targeted support and improvement by a State that has developed and is implementing a school-level targeted support and improvement plan to improve student outcomes based on the indicators in the statewide accountability system as defined in section 1111(d)(2) of the ESEA.

scholar support. Applicants proposing to use year one for program development may budget for less than 65 percent of the total requested budget over the 5 years for scholar support; such applicants must ensure that 65 percent of the total award minus funds allocated for program development will be used for scholar support;

(9) Ensure that the IHE at which scholars are enrolled in the program will not require those scholars to work (*e.g.,* as graduate assistants) as a condition of receiving support (*e.g.,* tuition, stipends) from the proposed project, unless the work is specifically related to the acquisition of scholars' competencies or the requirements for completion of their personnel preparation program. This prohibition on work as a condition of receiving support does not apply to the service obligation requirements in section 662(h) of IDEA;

(10) Ensure that scholar support costs (*e.g.,* tuition, stipends) are scholarship assistance and not financial assistance based on the condition that the scholar work (*e.g.,* as graduate assistants);

(11) Ensure that the budget includes attendance of the project director at a three-day project directors' meeting in Washington, DC during each year of the project. The project must reallocate funds for travel to the project directors' meeting no later than the end of the third quarter of each budget period if the meeting is conducted virtually;

(12) Ensure that the project director, key personnel, and, as appropriate, scholars will actively participate in cross-project collaboration opportunities, advanced trainings, and other learning opportunities (*e.g.,* webinars, briefings) organized by OSEP. This network will be used to build capacity of participants, increase the impact of funding, and promote innovative service delivery models;

(13) Ensure that if the project maintains a website, relevant information and documents are in a format that meets government or industry-recognized standards for accessibility; and

(14) Ensure that annual data will be submitted on each scholar who receives grant support (OMB Control Number 1820–0686). The primary purposes of the data collection are to track the service obligation fulfillment of scholars who receive funds from OSEP grants and to collect data for program performance measure reporting under 34 CFR 75.110. Applicants are encouraged to visit the Personnel Development Program Data Collection System (DCS) website at *https://pdp.ed.gov/osep* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant, although grantees may submit data as needed, year round. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590). Data collection includes the submission of a signed, completed Pre-Scholarship Agreement and Exit Certification for each scholar funded under an OSEP grant (see paragraph (5) of these requirements).

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U.S. Department of Education. (2020). EDFacts Data Warehouse: ''IDEA Part B Child Count and Educational Environments Collection'' & ''IDEA Part C Child Count and Settings Collection,'' 2019–20. *www2.ed.gov/programs/osepidea/618-data/static-tables/index.html.*

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priorities in this notice.

Program Authority: 20 U.S.C. 1462 and 1481.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 304.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $250,000,000 for the Personnel Development to Improve Services and Results for Children with Disabilities program for FY 2022, of which we intend to use an estimated $9,500,000 for this competition. The actual level of funding, if any, depends on final

congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2023 from the list of unfunded applications from this competition.

Estimated Range of Awards: $200,000–$250,000 per year.

Estimated Average Size of Awards: $225,000 per year.

Maximum Award: We will not make an award exceeding $250,000 for a single budget period of 12 months.

Estimated Number of Awards: 38.

Project Period: Up to 60 months.

Note: The Department is not bound by any estimates in this notice.

III. Eligibility Information

1. *Eligible Applicants:* For Absolute Priority 1, eligible applicants are IHEs and private nonprofit organizations. For Absolute Priority 2, eligible applicants are MSIs and private nonprofit organizations.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* Cost sharing or matching is not required for this competition.

b. *Indirect Cost Rate Information:* This program uses a training indirect cost rate. This limits indirect cost reimbursement to an entity's actual indirect costs, as determined in its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. For more information regarding training indirect cost rates, see 34 CFR 75.562. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application. Under 34 CFR 75.708(e), a grantee may contract for supplies, equipment, and other services in accordance with 2 CFR part 200.

4. *Other General Requirements:*

a. Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

b. Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 27, 2021 (86 FR 73264) and available at *www.federalregister.gov/d/2021-27979*, which contain requirements and information on how to submit an application. Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov* a DUNS number to the implementation of the UEI. More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) *Significance (10 points).*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which the proposed project will prepare personnel for fields in which shortages have been demonstrated; and

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project, especially improvements in teaching and student achievement.

(b) *Quality of project services (45 points).*

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the

quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In determining the quality of the project services, the Secretary considers the following factors:

(i) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice;

(ii) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services;

(iii) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services; and

(iv) The extent to which the proposed activities constitute a coherent, sustained program of training in the field.

(c) *Quality of the project evaluation (25 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project;

(ii) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable;

(iii) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible; and

(iv) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(d) *Quality of project personnel, quality of the management plan, and adequacy of resources (20 points).*

(1) The Secretary considers the quality of the project personnel, the quality of the management plan, and the adequacy of resources for the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of key project personnel;

(ii) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks;

(iii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project;

(iv) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization; and

(v) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions, and under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

6. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works.

Additionally, a grantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* For the purposes of Department reporting under 34 CFR 75.110, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Personnel Development to Improve Services and Results for Children with Disabilities program. These measures include (1) the percentage of preparation programs that incorporate scientifically or evidence-based practices into their curricula; (2) the percentage of scholars completing the preparation program who are knowledgeable and skilled in evidence-based practices that improve outcomes for children with disabilities; (3) the percentage of scholars who exit the preparation program prior to completion due to poor academic performance; (4) the percentage of scholars completing the preparation program who are working in the area(s) in which they were prepared upon program completion; (5) the Federal cost per scholar who completed the preparation program; (6) the percentage of scholars who completed the preparation program and are employed in high-need districts; and (7) the percentage of scholars who completed the preparation program and who are rated effective by their employers.

In addition, the Department will gather information on the following outcome measures: The number and percentage of scholars proposed by the grantee in their application that were actually enrolled and making satisfactory academic progress in the current academic year; the number and percentage of enrolled scholars who are on track to complete the training program by the end of the project's original grant period; and the percentage of scholars who completed the preparation program and are employed in the field of special education for at least two years.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

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

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

Katherine Neas,

Deputy Assistant Secretary, delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2022–02392 Filed 2–3–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0134]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; National Evaluation of the 2019 Comprehensive Centers Program Grantees

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new collection.

DATES: Interested persons are invited to submit comments on or before March 7, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Andrew Abrams, 202–245–7500.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: National Evaluation of the 2019 Comprehensive Centers Program Grantees.

OMB Control Number: 1850–NEW.

Type of Review: New collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 259.

Total Estimated Number of Annual Burden Hours: 106.

Abstract: The 2015 update to the federal law governing K–12 schooling gave state (SEAs) and local education agencies (LEAs) increased responsibilities, and, therefore, extra demands on their time and capabilities. The Comprehensive Centers program, funded by the U.S. Department of Education at over $50 million per year, provides training, tools, and other supports to help these agencies carry out their education plans and take steps to close achievement gaps. The Centers' services aim to build individual and organizational capacity to help identify and solve key problems. This evaluation will examine the delivery and usefulness of the Centers' technical assistance, given potential new stakeholder needs and changes in the Center program that took effect with the 20 new grants awarded in in 2019. Congress requires a periodic evaluation of the Comprehensive Centers program, with the results intended to inform ongoing program improvements.

Dated: February 1, 2022.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–02391 Filed 2–3–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 6240–064]

Watson Associates; Notice Soliciting Scoping Comments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 6240–064.

c. *Date Filed:* August 27, 2021.

d. *Applicant:* Watson Associates.

e. *Name of Project:* Watson Dam Project.

f. *Location:* On the Cocheco River in Strafford County, New Hampshire. The project does not occupy any federal land.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. John Webster, Watson Associates, P.O. Box 178, South Berwick, ME 03908; Phone at (207) 384–5334, or email at *Hydromagnt@gwi.net.*

i. *FERC Contact:* Michael Watts at (202) 502–6123, or *michael.watt@ferc.gov.*

j. *Deadline for filing scoping comments:* March 2, 2022.

The Commission strongly encourages electronic filing. Please file scoping comments using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* 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, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Watson Dam Project (P–6240–064).

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 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. The application is not ready for environmental analysis at this time.

l. The existing Watson Dam Project (Figure 2) consists of: (1) A 292.5-foot-long, 12-foot-high concrete gravity dam that includes the following sections: (a) A 54-foot-long right abutment; (b) a 111-foot-long right spillway section with 24-inch-high flashboards and a crest elevation of 110.1 North American Vertical Datum of 1988 (NAVD 88) at the top of the flashboards; (c) a 12-foot-long, 11. 5-foot-wide concrete spillway center pier; (d) an 80-foot-long left spillway section with 24-inch-high flashboards and a crest elevation of 110.2 feet NAVD 88 at the top of the flashboards; and (e) a 24-foot-long left abutment; (2) an impoundment with a surface area of 54 acres and a storage capacity of 300 acre-feet at an elevation of 110.1 feet NAVD 88; (3) a 26-foot-long, 24-foot-wide intake structure in the left abutment that is equipped with an 8.5-foot-diameter headgate and trashrack with 2-inch clear bar spacing; (4) a 26.5-foot-long, 34-foot-wide wood and steel powerhouse containing one 265-kilowatt vertical Flygt submersible turbine-generator unit; (5) a 250-foot-long, 20-foot-wide tailrace that discharges into the Cocheco River; (6) a 0.48/12.47-kilovolt (kV) step-up transformer and an 80-foot-long, 12.47 kV transmission line that connect the project to the local utility distribution system; and (7) appurtenant facilities. The project creates an approximately 250-foot-long and a 400-foot-long bifurcated bypassed reaches of the Cocheco River.

Watson Associates voluntarily operates the project in a run-of-river mode using an automatic pond level control system to regulate turbine operation, such that outflow from the project approximates inflow. Downstream fish passage is provided by a bypass facility located next to the project's intake on the left side of the dam. There is no upstream fish passage facility at the project.

Article 26 of the current license requires a minimum flow of 83 cfs or inflow to the impoundment, whichever is less, from the project, to protect and enhance aquatic resources in the Cocheco River. Watson Associates is required to operate the downstream fish passage facility from October 1 through November 15 of each year.

The average annual energy production of the project is approximately 1,100. MWh.

Watson Associates proposes to: (1) Continue to operate the project in a run-of-river mode; (2) continue to provide downstream fish passage through the bypass facility; and (3) consult with the New Hampshire State Historic Preservation Officer before beginning any land-disturbing activities or alterations to known historic structures within the project boundary.

m. 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 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. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TYY, (202) 502–8659.

n. You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. Scoping Process.

Commission staff will prepare either an environmental assessment (EA) or an Environmental Impact Statement (EIS) that describes and evaluates the probable effects, if any, of the licensee's proposed action and alternatives. The EA or EIS will consider environmental impacts and reasonable alternatives to the proposed action. The Commission's scoping process will help determine the required level of analysis and satisfy the NEPA scoping requirements, irrespective of whether the Commission prepares an EA or an EIS. At this time, we do not anticipate holding on-site scoping meetings. Instead, we are soliciting written comments and suggestions on the preliminary list of issues and alternatives to be addressed in the NEPA document, as described in scoping document 1 (SD1), issued January 31, 2022.

Copies of the SD1 outlining the subject areas to be addressed in the NEPA document were distributed to the parties on the Commission's mailing list and the applicant's distribution list. Copies of SD1 may be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call 1–866–208–3676 or for TTY, (202) 502–8659.

Dated: January 31, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–02372 Filed 2–3–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–922–000]

United Energy Partners, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of United Energy Partners, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is February 22, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the

FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

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 TYY, (202) 502–8659.

Dated: January 31, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–02385 Filed 2–3–22; 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 rate filings:

Docket Numbers: ER15–1905–009.
Applicants: AZ721 LLC.
Description: Notice of Change in Status of Amazon Energy LLC.
Filed Date: 1/28/22.
Accession Number: 20220128–5432.
Comment Date: 5 p.m. ET 2/18/22.

Docket Numbers: ER17–215–001.
Applicants: Midcontinent Independent System Operator, Inc., Great River Energy, South Mississippi Electric Power Association.
Description: Compliance filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35: 2022–01–31_ROE Compliance Filing to be effective 9/28/2016.
Filed Date: 1/31/22.
Accession Number: 20220131–5245.
Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER21–2581–002.
Applicants: Southwest Power Pool, Inc.
Description: Compliance filing: Compliance Filing In Response to Order Issued in ER21–2581 (COI/IPL) to be effective 10/1/2021.
Filed Date: 1/31/22.
Accession Number: 20220131–5286.
Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–924–000.
Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: American Transmission Systems, Incorporated submits tariff filing per 35.13(a)(2)(iii: ATSI submits four ECSAs, SA Nos. 6151, 6152, 6283 and 6284 to be effective 3/30/2022.
Filed Date: 1/28/22.
Accession Number: 20220128–5378.
Comment Date: 5 p.m. ET 2/18/22.

Docket Numbers: ER22–925–000.
Applicants: Tucson Electric Power Company.
Description: § 205(d) Rate Filing: Service Agreement Nos. 492 and 493 to be effective 1/1/2022.
Filed Date: 1/28/22.
Accession Number: 20220128–5387.
Comment Date: 5 p.m. ET 2/18/22.

Docket Numbers: ER22–926–000.
Applicants: Flanders Energy LLC.
Description: Notice of Cancellation of Market Based Rate Tariff of Flanders Energy LLC.
Filed Date: 1/28/22.
Accession Number: 20220128–5431.
Comment Date: 5 p.m. ET 2/18/22.

Docket Numbers: ER22–927–000.
Applicants: ISO New England Inc., New England Power Company.
Description: § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: ISO–NE and NEP; Third Revised Service Agreement Nos. TSA–NEP–83 and TSA–NEP–86 to be effective 1/1/2022.
Filed Date: 1/31/22.
Accession Number: 20220131–5073.
Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–928–000.
Applicants: Pacific Gas and Electric Company.
Description: § 205(d) Rate Filing: Q4 2021 Quarterly Filing of City and County of San Francisco's WDT SA (SA 275) to be effective 12/31/2021.
Filed Date: 1/31/22.
Accession Number: 20220131–5120.
Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–929–000.
Applicants: Midcontinent Independent System Operator, Inc., Michigan Electric Transmission Company, LLC, Consumers Energy Company.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2022–01–31_SA 1926 METC–CE 8th Rev DTIA to be effective 1/1/2022.
Filed Date: 1/31/22.
Accession Number: 20220131–5181.
Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–930–000.
Applicants: American Transmission Systems, Incorporated, The Cleveland Electric Illuminating Company, Ohio Edison Company, Pennsylvania Power Company, The Toledo Edison Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: American Transmission Systems, Incorporated submits tariff filing per 35.13(a)(2)(iii: FirstEnergy submits on behalf of ATSI et al. SA No. 2853 to be effective 4/2/2022.
Filed Date: 1/31/22.
Accession Number: 20220131–5202.
Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–931–000.
Applicants: AV Solar Ranch 1, LLC.
Description: § 205(d) Rate Filing: Notice of Change in Status, Revised MBR Tariffs and Request for Waiver to be effective 2/1/2022.
Filed Date: 1/31/22.
Accession Number: 20220131–5211.
Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–932–000.
Applicants: Constellation Energy Commodities Group Maine, LLC.
Description: § 205(d) Rate Filing: Notice of Change in Status, Revised MBR Tariffs and Request for Waiver to be effective 2/1/2022.
Filed Date: 1/31/22.
Accession Number: 20220131–5215.
Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–933–000.
Applicants: Constellation NewEnergy, Inc.
Description: § 205(d) Rate Filing: Notice of Change in Status, Revised MBR Tariffs and Request for Waiver to be effective 2/1/2022.
Filed Date: 1/31/22.
Accession Number: 20220131–5216.
Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–934–000.
Applicants: Exelon Generation Company, LLC.

Description: § 205(d) Rate Filing: Notice of Change in Status, Revised MBR Tariffs and Request for Waiver to be effective 2/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5219.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–935–000.

Applicants: Virginia Electric and Power Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Virginia Electric and Power Company submits tariff filing per 35.13(a)(2)(iii): Second Revised Service Agreement No. 3226, NITSA Between to be effective 1/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5224.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–936–000.

Applicants: Flat Ridge Interconnection LLC.

Description: § 205(d) Rate Filing: Filing of Revised Rate Schedule and Request for Waivers to be effective 4/2/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5229.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–937–000.

Applicants: New Market Solar ProjectCo 1, LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rates, Waivers and Authority to be effective 3/15/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5293.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–938–000.

Applicants: New Market Solar ProjectCo 2, LLC.

Description: Baseline eTariff Filing: Application for MBR, Waivers and Authority to be effective 3/15/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5296.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–939–000.

Applicants: Zimmer Power Company LLC.

Description: Tariff Amendment: Notice of Cancellation to be effective 5/31/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5299.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–940–000.

Applicants: Northern Indiana Public Service Company LLC.

Description: § 205(d) Rate Filing: Yellow_River CIAC Agreement to be effective 2/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5311.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–941–000.

Applicants: Arlington Wind Power Project LLC.

Description: Compliance filing: Notice of Change in Category Seller Status in the NW Region to be effective 2/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5318.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–942–000.

Applicants: Sagebrush Power Partners, LLC.

Description: Compliance filing: Notice of Change in Category Seller Status in the NW Region to be effective 2/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5322.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–943–000.

Applicants: Wheat Field Wind Power Project LLC.

Description: Compliance filing: Notice of Change in Category Seller Status in the NW Region to be effective 2/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5325.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–944–000.

Applicants: Black Rock Wind Force, LLC.

Description: Initial rate filing: Filing of Reactive Power Rate Schedule to be effective 3/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5327.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–945–000.

Applicants: New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: February 2022 Membership Filing to be effective 1/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5340.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–946–000.

Applicants: South Jersey Energy Company.

Description: Tariff Amendment: Cancellation of MBR Tariff to be effective 2/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5348.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–947–000.

Applicants: South Jersey Energy ISO1, LLC.

Description: Tariff Amendment: Cancellation of Complete Tariff to be effective 2/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5350.

Comment Date: 5 p.m. ET 2/22/22.

Docket Numbers: ER22–948–000.

Applicants: South Jersey Energy ISO3, LLC.

Description: Tariff Amendment: Cancellation of MBR Tariff to be effective 2/1/2022.

Filed Date: 1/31/22.

Accession Number: 20220131–5359.

Comment Date: 5 p.m. ET 2/22/22.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES22–27–000.

Applicants: Evergy Missouri West, Inc.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Evergy Missouri West, Inc.

Filed Date: 1/28/22.

Accession Number: 20220128–5311.

Comment Date: 5 p.m. ET 2/18/22.

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: *https://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: January 31, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–02382 Filed 2–3–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Order on Intent To Revoke Market-Based Rate Authority

Before Commissioners: Richard Glick, Chairman; James P. Danly, Allison Clements, Mark C. Christie, and Willie L. Phillips.

	Docket Nos.
Electric Quarterly Reports; Liberty Power Delaware LLC; Liberty Power Wholesale Supply, LLC; Entrust Energy East, Inc.; PowerOne Corporation.	ER02–2001–020; ER12–2401–000; ER12–1707–000; ER15–1557–001; ER14–209–001.

1. Section 205 of the Federal Power Act (FPA), 16 U.S.C. 824d, and 18 CFR part 35 (2021), require, among other things, that all rates, terms, and conditions for jurisdictional services be filed with the Commission. In Order No. 2001, the Commission revised its public utility filing requirements and established a requirement for public utilities, including power marketers, to file Electric Quarterly Reports.[1]

2. The Commission requires sellers with market-based rate authorization to file Electric Quarterly Reports summarizing contractual and transaction information related to their market-based power sales as a condition for retaining that authorization.[2] Commission staff's review of the Electric Quarterly Reports indicates that the following four public utilities with market-based rate authorization have failed to file their Electric Quarterly Reports: Liberty Power Delaware LLC, Liberty Power Wholesale Supply, LLC, Entrust Energy East, Inc., and PowerOne Corporation. This order notifies these public utilities that their market-based rate authorizations will be revoked unless they comply with the Commission's requirements within 15 days of the date of issuance of this order.

3. In Order No. 2001, the Commission stated that,

> [i]f a public utility fails to file a[n] Electric Quarterly Report (without an appropriate request for extension), or fails to report an agreement in a report, that public utility may forfeit its market-based rate authority and may be required to file a new application for market-based rate authority if it wishes to resume making sales at market-based rates.[3]

4. The Commission further stated that,

> [o]nce this rule becomes effective, the requirement to comply with this rule will supersede the conditions in public utilities' market-based rate authorizations, and failure to comply with the requirements of this rule will subject public utilities to the same consequences they would face for not satisfying the conditions in their rate authorizations, including possible revocation of their authority to make wholesale power sales at market-based rates.[4]

5. Pursuant to these requirements, the Commission has revoked the market-based rate tariffs of market-based rate sellers that failed to submit their Electric Quarterly Reports.[5]

6. Sellers must file Electric Quarterly Reports consistent with the procedures set forth in Order Nos. 2001, 768,[6] and 770.[7] The exact filing dates for Electric Quarterly Reports are prescribed in 18 CFR 35.10b. As noted above, Commission staff's review of the Electric Quarterly Reports for the period up to the third quarter of 2021 identified four public utilities with market-based rate authorization that failed to file Electric Quarterly Reports. Commission staff contacted or attempted to contact these entities to remind them of their regulatory obligations. Despite these reminders, the public utilities listed in the caption of this order have not met these obligations. Accordingly, this order notifies these public utilities that their market-based rate authorizations will be revoked unless they comply with the Commission's requirements within 15 days of the issuance of this order.

7. In the event that any of the above-captioned market-based rate sellers has already filed its Electric Quarterly Reports in compliance with the Commission's requirements, its inclusion herein is inadvertent. Such market-based rate seller is directed, within 15 days of the date of issuance of this order, to make a filing with the Commission identifying itself and providing details about its prior filings that establish that it complied with the Commission's Electric Quarterly Report filing requirements.

8. If any of the above-captioned market-based rate sellers does not wish to continue having market-based rate authority, it may file a notice of cancellation with the Commission pursuant to section 205 of the FPA to cancel its market-based rate tariff.

The Commission orders:

(A) Within 15 days of the date of issuance of this order, each public utility listed in the caption of this order shall file with the Commission all delinquent Electric Quarterly Reports. If a public utility subject to this order fails to make the filings required in this order, the Commission will revoke that public utility's market-based rate authorization and will terminate its electric market-based rate tariff. The Secretary is hereby directed, upon expiration of the filing deadline in this order, to promptly issue a notice, effective on the date of issuance, listing the public utilities whose tariffs have been revoked for failure to comply with the requirements of this order and the Commission's Electric Quarterly Report filing requirements.

(B) The Secretary is hereby directed to publish this order in the **Federal Register**.

By the Commission.

Issued: January 31, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–02361 Filed 2–3–22; 8:45 am]

BILLING CODE 6717–01–P

[1] *Revised Public Utility Filing Requirements,* Order No. 2001, 99 FERC ¶ 61,107, *reh'g denied,* Order No. 2001–A, 100 FERC ¶ 61,074, *reh'g denied,* Order No. 2001–B, 100 FERC ¶ 61,342, *order directing filing,* Order No. 2001–C, 101 FERC ¶ 61,314 (2002), *order directing filing,* Order No. 2001–D, 102 FERC ¶ 61,334, *order refining filing requirements,* Order No. 2001–E, 105 FERC ¶ 61,352 (2003), *order on clarification,* Order No. 2001–F, 106 FERC ¶ 61,060 (2004), *order revising filing requirements,* Order No. 2001–G, 120 FERC ¶ 61,270, *order on reh'g and clarification,* Order No. 2001–H, 121 FERC ¶ 61,289 (2007), *order revising filing requirements,* Order No. 2001–I, 125 FERC ¶ 61,003 ¶ 31,282 (2008). *See also Filing Requirements for Electric Utility Service Agreements,* 155 FERC ¶ 61,280, *order on reh'g and clarification,* 157 FERC ¶ 61,180 (2016) (clarifying Electric Quarterly Reports reporting requirements and updating Data Dictionary).

[2] *See Refinements to Policies & Procedures for Mkt.-Based Rates for Wholesale Sales of Elec. Energy, Capacity & Ancillary Servs. by Pub. Utilils.,* Order No. 816, 153 FERC ¶ 61,065, at P 353 (2015), *order on reh'g,* Order No. 816–A, 155 FERC ¶ 61,188 (2016); *Mkt.-Based Rates for Wholesale Sales of Elec. Energy, Capacity & Ancillary Servs. by Pub. Utils.,* Order No. 697, 119 FERC ¶ 61,295, at P 882, *clarified,* 121 FERC ¶ 61,260 (2007), *order on reh'g,* Order No. 697–A, 123 FERC ¶ 61,055, *clarified,* 124 FERC ¶ 61,055, *order on reh'g,* Order No. 697–B, 125 FERC ¶ 61,326 (2008), *order on reh'g,* Order No. 697–C, 127 FERC ¶ 61,284 (2009), *order on reh'g,* Order No. 697–D, 130 FERC ¶ 61,206 (2010), *aff'd sub nom. Mont. Consumer Counsel* v. *FERC,* 659 F.3d 910 (9th Cir. 2011).

[3] Order No. 2001, 99 FERC ¶ 61,107 at P 222.

[4] *Id.* P 223.

[5] *See, e.g., Electric Quarterly Reports,* 82 FR 60,976 (Dec. 26, 2017); *Electric Quarterly Reports,* 80 FR 58,243 (Sep. 28, 2015); *Electric Quarterly Reports,* 79 FR 65,651 (Nov. 5, 2014).

[6] *Electricity Market Transparency Provisions of Section 220 of the Federal Power Act,* Order No. 768, 140 FERC ¶ 61,232 (2012), *order on reh'g,* Order No. 768–A, 143 FERC ¶ 61,054 (2013), *order on reh'g,* Order No. 768–B, 150 FERC ¶ 61,075 (2015).

[7] *Revisions to Electric Quarterly Report Filing Process,* Order No. 770, 141 FERC ¶ 61,120 (2012).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0751; FRL–9437–01–OCSPP]

Pesticide Registration Review; Interim Decisions and Final Decision for Several Pesticides; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's interim registration review decisions for the following chemicals: Creosote; and chromated arsenicals and dichromic acid, disodium salt, dehydrate. In addition, it announces the final registration review decision for pentachlorophenol.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the pesticide specific contact person listed in Table 1 in Unit IV.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

For general information on the registration review program, contact: Kimberly Wilson, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0647; email address: *wilson.kimberly@epa.gov.*

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed interim and final decisions for all pesticides listed in Table 1 in Unit IV. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

III. Authority

EPA is conducting its registration review of the chemicals listed in Table 1 in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's interim and final registration review decisions for the pesticides shown in Table 1. The interim and final registration review decisions are supported by rationales included in the docket established for each chemical.

TABLE 1—REGISTRATION REVIEW INTERIM AND FINAL DECISIONS BEING ISSUED

Registration review case name and No.	Docket ID No.	Chemical Review Manager and contact information
Creosote, Case 0139	EPA–HQ–OPP–2014–0823	Peter Bergquist, *bergquist.peter@epa.gov,* (202) 566–0648.
Chromated Arsenicals, Case 0132 [a]	EPA–HQ–OPP–2015–0349	Peter Bergquist, *bergquist.peter@epa.gov,* (202) 566–0648.
Dichromic acid, disodium salt, dehydrate, Case 5012 [a]	EPA–HQ–OPP–2010–0243	Peter Bergquist, *bergquist.peter@epa.gov,* (202) 566–0648.
Pentachlorophenol, Case 2505	EPA–HQ–OPP–2014–0653	Peter Bergquist, *bergquist.peter@epa.gov,* (202) 566–0648.

[a] The Interim Decisions for chromated arsenicals and dichromic acid, disodium salt, dihydrate will be released in a single document available in the dockets for both cases.

The proposed interim registration review decisions for the chemicals in the table above were posted to the docket and the public was invited to submit any comments or new information. EPA addressed the comments or information received during the 75-day comment period for the proposed interim decisions in the discussion for each pesticide listed in the table. Comments from the 75-day comment period that were received may or may not have affected the Agency's interim or final decisions. Pursuant to 40 CFR 155.58(c), the registration review case docket for the chemicals listed in the Table will remain open until all actions required in the interim decision have been completed.

Background on the registration review program is provided at: *http://www.epa.gov/pesticide-reevaluation.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: January 25, 2022.

Anita Pease,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2022–02418 Filed 2–3–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–002]

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 January 24, 2022 10 a.m. EST

Through January 31, 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://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20220011, Draft, USN, HI, Pearl Harbor Naval Shipyard and Intermediate Maintenance Facility Dry Dock and Waterfront Production Facility at Joint Base Pearl Harbor-Hickam, Oahu, Hawaii, Comment Period Ends: 03/21/2022, Contact: Andrea Von Burg Hall 808–472–1425.

EIS No. 20220012, Second Draft Supplemental, USACE, FL, Port Everglades Harbor, Broward County, Florida, Comment Period Ends: 03/21/2022, Contact: Paul Demarco 904–232–1897.

Dated: January 31, 2022.

Candi Schaedle,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2022–02375 Filed 2–3–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1263; FR ID 70086]

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 Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. 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 OMB 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 OMB control number.

DATES: Written PRA comments should be submitted on or before April 5, 2022. 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 Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1263.

Title: Sections 74.1203(a)(3), Interference, and 74.1204(f), Protection of FM broadcast, FM Translator and LP100 stations.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 270 respondents; 270 responses.

Estimated Time per Response: 3–5 hours.

Frequency of Response: Third party disclosure requirement and on occasion reporting requirement.

Total Annual Burden: 1,080 hours.

Total Annual Cost: $924,100.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 1, 4(i), 4(j), 301, 303, 307, 308, 309, 316, and 319 of the Communications Act, 47 U.S.C. 151, 154(i), 154(j), 301, 303, 307, 308, 309, 316, and 319.

Needs and Uses: On May 9, 2019, the Commission adopted a Report and Order, Amendment of Part 74 of the Commission's Rules Regarding FM Translator Interference, FCC 19–40, MB Docket No. 18–119 (FM Translator Interference Report and Order), adopting proposals to streamline the rules relating to interference caused by FM translators and to expedite the translator interference complaint resolution process. These measures are designed to limit or avoid protracted and contentious interference disputes, provide translator licensees additional investment certainty and flexibility to remediate interference, and provide affected stations earlier and expedited resolution of interference complaints. Under this new information collection, the following information collection requirements require OMB approval.

Specifically, the FM Translator Interference Report and Order pertains to this new Information Collection as it codifies the translator interference listener complaint requirements under section 74.1201(k) and sections 74.1203(a)(3) (actual interference) and 74.1204(f) (predicted interference) of the rules. The Commission defines the requirements for a listener complaint submitted with a translator interference claim in section 74.1201(k) as a complaint that is signed and dated by the listener and contains the following information: (1) The complainant's full name, address, and phone number; (2) a clear, concise, and accurate description of the location where the interference is alleged to occur; (3) a statement that the complainant listens to the desired station using an over-the-air signal at least twice a month, to demonstrate the complainant is a regular listener; and (4) a statement that the complainant has no legal, employment, financial, or familial affiliation or relationship with the desired station, to demonstrate the complainant is disinterested. Electronic signatures are acceptable for this purpose.

The FM Translator Interference Report and Order establishes a minimum number of listener complaints ranging from 6 to 25 depending on the population served within the protected contour of the complaining station. The Commission explains that a proportionate approach, which was supported by multiple commenters, would be fairer and more effective than a single minimum number for all

complaining stations. In addition to the required minimum number of valid listener statements, a station submitting a translator interference claim package pursuant to either section 74.1203(a)(3) or 74.1204(f) must include: (1) A map plotting the specific locations of the alleged interference in relation to the 45 dBu contour of the complaining station; (2) a statement that the complaining station is operating within its licensed parameters; (3) a statement that the complaining station licensee has used commercially reasonable efforts to inform the relevant translator licensee of the claimed interference and attempted private resolution; and (4) U/D data demonstrating that at each listener location the ratio of undesired to desired signal strength exceeds –20 dB for co-channel situations, –6 dB for first-adjacent channel situations or 40 dB for second- or third-adjacent channel situations, calculated using the Commission's standard contour prediction methodology set out in Section 73.313.

In the FM Translator Interference Report and Order, the Commission outlines two paths for resolving interference if the translator decides to continue operation on its original channel. First, a translator operator may resolve each listener complaint by working with a willing listener to resolve reception issues. The translator operator must then document and certify that the desired station can now be heard on the listener's receiver, *i.e.,* that the adjustment to or replacement of the listener's receiving equipment actually resolved the interference. Second, the translator operator may work with the complaining station to resolve station signal interference issues using rule-compliant suitable technical techniques. (The Commission provides flexibility to the parties to determine the testing parameters for demonstrating that the interference has been resolved, for example, the use of on-off testing or field strength measurements.) Once agreement is reached, the translator operator submits the agreed-upon remediation showing to the Commission.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–02326 Filed 2–3–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[GN Docket No. 17–208; FRS 17381]

Meeting of the Communications Equity and Diversity Council

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces the February 23, 2022, meeting of the Federal Communications Commission's (Commission) Communications Equity and Diversity Council (CEDC or Council).

DATES: Wednesday, February 23, from 10:00 a.m. ET to 4:00 p.m. ET.

ADDRESSES: The CEDC meeting will be held virtually and be available to the public for viewing via the internet at *http://www.fcc.gov/live.*

FOR FURTHER INFORMATION CONTACT: Jamila Bess Johnson, Designated Federal Officer (DFO) of the CEDC, (202) 418–2608, *Jamila-Bess.Johnson@fcc.gov;* Rashann Duvall, Co-Deputy DFO of the CEDC, (202) 418–1438, *Rashann.Duvall@fcc.gov;* or, Keyla Hernandez-Ulloa, Co-Deputy DFO of the CEDC, (202) 418–0965, *Keyla.Hernandez-Ulloa@fcc.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Agenda: The agenda for the meeting will include a discussion of the proposed workstreams for the three CEDC working groups (Innovation and Access, Digital Empowerment and Inclusion, and Diversity and Equity) during the two-year charter. The workstreams will provide a roadmap for how each working group will support the Council's mission to make recommendations to the Commission on advancing equity in the provision of, and access to, digital communication services and products for all people of the United States, without discrimination on the basis of race, color, religion, national origin, sex, or disability. This agenda may be modified at the discretion of the CEDC Chair and the DFO. The CEDC meeting will be accessible to the public on the internet via live feed from the Commission's web page at *www.fcc.gov/live.* Members of the public may submit questions during the meeting to *livequestions@fcc.gov.* Oral statements at the meeting by parties or entities not represented on the CEDC will be permitted to the extent time permits and at the discretion of the CEDC Chair and the DFO.

Members of the public may submit comments to the CEDC using the FCC's Electronic Comment Filing System, ECFS, at *www.fcc.gov/ecfs.* Comments to the CEDC should be filed in GN Docket No. 17–208.

Open captioning will be provided for this event. Other reasonable accommodations for persons with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). Such requests should include a detailed description of the accommodation needed. In addition, please include a way for the Commission to contact the requester if more information is needed to fulfill the request. Please allow at least five days' notice; last minute requests will be accepted but may not be possible to accommodate.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

[FR Doc. 2022–02335 Filed 2–3–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1765]

Framework for the Supervision of Insurance Organizations

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Proposed guidance; request for comments.

SUMMARY: The Board is seeking comment on a new supervisory framework for depository institution holding companies significantly engaged in insurance activities, or supervised insurance organizations. The proposed framework would provide a supervisory approach that is designed specifically to reflect the differences between banking and insurance. Within the framework, the application of supervisory guidance and the assignment of supervisory resources would be based explicitly on a supervised insurance organization's complexity and individual risk profile. The proposed framework would formalize the ratings applicable to these firms with rating definitions that reflect specific supervisory requirements and expectations. It would also emphasize the Board's policy to rely to the fullest extent possible on work done by other relevant supervisors, describing, in particular, the way it will rely more fully on reports and other supervisory information provided by state insurance

regulators to minimize the burden associated with supervisory duplication.

DATES: Comments must be received no later than April 5, 2022.

ADDRESSES: You may submit comments, identified by Docket No. OP–1765, by any of the following methods:

Agency website: https://www.federalreserve.gov. Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*

Email: regs.comments@federalreserve.gov. Include docket and RIN numbers in the subject line of the message.

Fax: (202) 452–3819 or (202) 452–3102.

Mail: Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed in-person in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. during federal business weekdays.

FOR FURTHER INFORMATION CONTACT: Thomas Sullivan, Senior Associate Director, (202) 475–7656; Matt Walker, Manager, (202) 872–4971; Brad Roberts, Lead Insurance Policy Analyst, (202) 452–2204; or Joan Sullivan, Senior Insurance Policy Analyst, (202) 912–4670, Division of Supervision and Regulation; or Charles Gray, Deputy General Counsel, (202) 872–7589; Andrew Hartlage, Senior Counsel, (202) 452–6483; or Christopher Danello, Senior Attorney, (202) 736–1960, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

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I. Background

The Board of Governors of the Federal Reserve System (Board) supervises and regulates companies that control one or more banks (bank holding companies) and companies that are not bank holding companies that control one or more savings associations (savings and loan holding companies, and together with bank holding companies, depository institution holding companies). Congress gave the Board regulatory and supervisory authority for bank holding companies through the enactment of the Bank Holding Company Act of 1956 (BHC Act).[1] The Board's regulation and supervision of savings and loan holding companies began in 2011 when provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) [2] transferring supervision and regulation of savings and loan holding companies from the Office of Thrift Supervision to the Board took effect.[3] Upon this transfer, the Board became the federal supervisory agency for all depository institution holding companies, including a portfolio of savings and loan holding companies significantly engaged in insurance activities (supervised insurance organizations).[4]

The Board has a long-standing policy of supervising holding companies on a consolidated basis. Consolidated supervision encompasses all legal entities within a holding company structure and supports an understanding of the organization's complete risk profile and its ability to address financial, managerial, operational, or other deficiencies before they pose a danger to its subsidiary depository institution(s). The Board's current supervisory approach for noninsurance depository institution holding companies assesses holding companies whose primary risks are related to the business of banking. The risks arising from insurance activities, however, are materially different from traditional banking risks. The top-tier holding company for some supervised insurance organizations is an insurance underwriting company, which is subject to supervision and regulation by the relevant state insurance regulator as well as consolidated supervision from the Board; for all of these firms, the state insurance regulators supervise and regulate the business of insurance underwriting companies. Additionally, instead of producing consolidated financial statements based on generally accepted accounting principles, many of these firms only produce legal entity financial statements based on Statutory Accounting Principles (SAP) established by states through the National Association of Insurance Commissioners (NAIC).

In view of these differences, the Board has sought to tailor its supervision and regulation of supervised insurance organizations. For example, in 2013, when the Board implemented the Basel III capital standard in the United States, the Board determined not to apply it to this group of companies, stating that it would ''explore further whether and how the proposed rule should be modified for these companies in a manner consistent with section 171 of the Dodd-Frank Act and safety and soundness concerns.'' [5] In 2019, the Board invited comment on a proposal to establish a risk-based capital framework designed specifically for supervised insurance organizations, termed the Building Block Approach, that would adjust and aggregate existing legal entity capital requirements to determine an enterprise-wide capital requirement.[6] In addition, in 2018, the Board did not apply to these firms the supervisory rating systems applicable to other depository institution holding companies.[7] As described in the Supplementary Information, the proposed supervisory framework (proposal) represents a significant step in the continuation of the Board's tailored approach to supervision and regulation for supervised insurance organizations.

II. Summary of the Proposal

The proposal would establish a transparent framework for consolidated supervision of supervised insurance organizations. A depository institution holding company is considered to be a supervised insurance organization if it

[1] Ch. 240, 70 Stat. 133.

[2] Public Law 111–203, 124 Stat. 1376 (2010).

[3] Dodd-Frank Act tit. III, 124 Stat. at 1520–70.

[4] Although currently all supervised insurance organizations are savings and loan holding companies, the proposed framework would apply to any depository institution holding company that meets the criteria of a supervised insurance organization.

[5] Regulatory Capital Rules: Implementation of Basel III, 78 FR 62017, 62027 (October 11, 2013).

[6] Regulatory Capital Rules: Risk-Based Capital Requirements for Depository Institution Holding Companies Significantly Engaged in Insurance Activities, 84 FR 57240 (October 24, 2019).

[7] See Large Financial Institution Rating System; Regulations K and LL, 83 FR 58724 (November 21, 2018); Application of the RFI/C(D) Rating System to Savings and Loan Holding Companies, 83 FR 56081 (November 9, 2018).

is an insurance underwriting company or if over 25 percent of its consolidated assets are held by insurance underwriting subsidiaries. The proposed framework is designed specifically to account for the unique risks and business profiles of supervised insurance organizations resulting mainly from their insurance business. The framework consists of a risk-based approach establishing supervisory expectations, assigning supervisory resources, and conducting supervisory activities; the formalization of a supervisory rating system; and a description of how examiners would work with state insurance regulators to limit the burden associated with supervisory duplication.

A. Proportionality

The proposed supervisory framework describes a supervisory approach that is proportional to the risks of each supervised insurance organization. This approach is designed to address the unique features of insurance activities and thereby not replicate the standards for the supervision of banking activities. The proposed supervisory framework would result in supervisory activities and the application of supervisory guidance that look beyond the size of the institution and instead focus on the material risks that could pose a threat to the organization's safety and soundness and, in particular, its ability to serve as a source of strength for its depository institution(s).

To achieve this, Federal Reserve staff would first classify supervised insurance organizations as either complex or noncomplex based on their risk profile. Supervisory activities would vary based on this determination and also based on each firm's individual risk profile. Complex supervised insurance organizations have a higher level of risk and therefore require more frequent and intense supervisory attention. Noncomplex supervised insurance organizations, due to their lower risk profile, require less intense supervisory oversight. In making this classification, the Federal Reserve would consider at least the factors listed in the proposal, which include: quality and level of capital and liquidity, size of its depository institution(s), organizational structure, unregulated and/or unsupervised activities, international exposure, product and portfolio risks, supervisory ratings and opinions, and interconnectedness.

Riskier firms would be classified as complex, which would result in the assignment of a dedicated team responsible for consolidated supervision of the organization. Complex firms would be subject to routine continuous monitoring and targeted examinations as necessary to properly understand and assess the firm. Less risky firms would be classified as noncomplex. Noncomplex firms would be subject to an annual examination to assess the firm and assign ratings. This approach make it possible for a firm with over $100 billion in total assets to be classified as noncomplex if, for example, most of those assets were a result of traditional insurance activities, it had a small depository institution, it had a history of maintaining relatively large capital and liquidity buffers, and it was viewed overall as well run with little risk to its depository institution. Supervisory activities would also be adapted among complex firms to reflect the actual risk profile of the firm and to focus on risks that are most likely to threaten the holding company's ability to act as a source of strength for its depository institution(s).

Applicable practices, as described in supervisory guidance, that are consistent with the Board's expectations for organizations operating in a safe and sound manner, would also vary based on the complexity classification and based on each firm's risk profile. The firm's risk profile would be reassessed by the Federal Reserve annually and Federal Reserve examiners would inform the firm if different supervisory guidance had become more relevant as a result of a material change to the firm's risk profile.

Question 1. What additional factors, if any, should the Board consider when considering the complexity of supervised insurance organizations?

Question 2. What other considerations beyond those outlined in this proposal should be considered in the Board's assessment of whether a supervised insurance organization has sufficient financial and operational strength and resilience to maintain safe and sound operations?

Question 3. What additional clarity, if any, is needed to describe the supervisory guidance related to the evaluation of a firm's governance and controls, capital management, and liquidity management under the proposed framework?

Question 4. What additional differences exist between supervised insurance organization and bank holding companies that should be considered and reflected in the framework? What additional measures, if any, could the Board take to appropriately tailor its approach to supervising these firms?

B. Ratings

Since 2011, supervised insurance organization have been assigned indicative ratings under the Board's RFIC/(D) framework (RFI framework).[8] The proposal would establish a unique supervisory rating system that, if adopted, would replace the indicative RFI ratings for all supervised insurance organizations. Under the proposed framework, firms would be rated annually in each of three components: Capital Management, Liquidity Management, and Governance and Controls. Firms would be assigned one of four ratings for each of the three components. The ratings are Broadly Meets Expectations, Conditionally Meets Expectations, Deficient-1, and Deficient-2 and would reflect how consistent a firm's practices are with the Board's expectations for safe and sound operations. As described above, despite rating the same components for all supervised insurance organizations and using the same ratings, applicable supervisory guidance would be based on each firm's specific risk profile and would vary significantly between the smallest, least risky firms and the largest, riskiest firms. The proposed ratings are modeled after the LFI framework, although they have been modified in structure and application to support their use for supervised insurance organizations of all sizes and risk profiles. For example, instead of emphasizing in the rating components and definitions the importance of continuing to serve as a financial intermediary under stress, the proposal stresses the obligation that supervised insurance organizations operate in a safe and sound manner and serve as a source of financial and managerial strength for their depository institution(s).

Question 5. What additional clarity, if any, is needed to describe the ratings process, including the ratings definitions?

Question 6. Should the final framework include a composite rating?

C. Incorporating the Work of Other Supervisors

Effective consolidated supervision requires collaborative relationships with all relevant supervisors and regulators. The Board respects the individual statutory authorities and responsibilities of other supervisors and regulators and works to develop appropriate information flows and coordination so

[8] SR 19–4: Supervisory Ratings System for Holding Companies with Total Consolidated Assets Less Than $100 billion, *https://www.federalreserve.gov/supervisionreg/srletters/sr1904.htm.*

that each supervisor's responsibilities can be carried out effectively while limiting the burden associated with supervisory duplication. In developing its overall assessment of a supervised insurance organization, the proposed framework emphasizes the importance of these relationships and that Federal Reserve examiners rely to the fullest extent possible on information available from, and examination reports by, other relevant supervisors and regulators. Because supervised insurance organizations have material insurance business lines, the proposed framework describes how the Federal Reserve would leverage the work done by the state insurance regulators, including examples of specifics insurance supervisory reports that will be used as input into the Federal Reserve's assessment and ratings. With respect to the business of insurance, the Board specifically leaves to the state insurance regulators the oversight of pricing and reserving of insurance liabilities.

Question 7. What additional measures, if any, should the Board take to fulfill its goal to rely to the fullest extent possible on work of other relevant supervisors, including the state insurance regulators?

III. Applicability, Timing, and Implementation

Federal Reserve examiners would use the proposed framework as their basis for the supervision of insurance organizations. A depository institution holding company is considered to be a supervised insurance organization if it is an insurance underwriting company or if over 25 percent of its consolidated assets are held by insurance underwriting subsidiaries. Other depository institution holding companies can also be designated as supervised insurance organizations if Federal Reserve staff decides, based on the firm's risk profile, that doing so would result in more effective supervision.

The Board proposes that the Federal Reserve would classify supervised insurance organizations as complex or noncomplex and initial ratings during the calendar year in which the final framework becomes effective. Due to differences in the timing of supervisory cycles across the portfolio, firms may receive their initial ratings at different times during the year.

Consistent with current Federal Reserve practice on the assignment and communication of supervisory ratings by examiners, ratings under the proposed framework would be assigned and communicated to firms on an annual basis, and more frequently as warranted. In accordance with the Board's regulations governing confidential supervisory information, ratings assigned under the proposed framework would be communicated by the Federal Reserve to the firm but not disclosed to other persons except in accordance with the Federal Reserve Act and the Board's Rules Regarding Availability of Information.[9]

Question 10. What additional clarity, if any, is needed to describe which firms would be subject to the proposed framework?

IV. Regulatory Analysis

Paperwork Reduction Act

There is no collection of information required by this proposal that would be subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

V. Proposed Text of the Supervisory Framework

This framework describes the Federal Reserve's approach to consolidated supervision of supervised insurance organizations.[1] The framework is designed specifically to account for the unique risks and business profiles of these firms resulting mainly from their insurance business. The framework consists of a risk-based approach to establishing supervisory expectations, assigning supervisory resources and conducting supervisory activities; a unique supervisory rating system; and a description of how Federal Reserve examiners will work with the state insurance regulators to limit the burden associated with supervisory duplication.

A. Proportionality—Supervisory Activities and Expectations

Consistent with the Federal Reserve's approach to risk-based supervision, supervisory guidance will be applied and supervisory activities will be conducted in a manner that is proportionate to each firm's individual risk profile. This begins by classifying each supervised insurance organization as either complex or noncomplex based on their risk profile and continues with a tailored application of supervisory guidance and supervisory activities. Federal Reserve supervisory teams will conduct a risk assessment each year based on their current understanding of the firm's risks. Any change in the risk assessment will be communicated to the firm's board and senior management, along with potential implications to the relevance of certain expectations communicated through supervisory guidance.[2] The risk assessment also drives supervisory activities, which will be focused on resolving supervisory knowledge gaps, monitoring the safety and soundness of the firm, and assessing the firm's management of risks that could potentially impact its ability to act as a source of managerial and financial strength for its depository institution(s).

1. Complex and Noncomplex Supervised Insurance Organizations

Each supervised insurance organization is classified by the Federal Reserve as either complex or noncomplex based on its risk profile. The classification serves as the basis for determining the level of supervisory resources dedicated to each firm, as well as the frequency and intensity of supervisory activities.

Complex: Complex firms have a higher level of risk and therefore require more frequent and intense supervisory attention. Federal Reserve dedicated supervisory teams are assigned to execute approved supervisory plans led by a dedicated Central Point of Contact. The activities listed in the supervisory plans focus on understanding any of a firm's risks that could threaten the safety and soundness of the consolidated organization or a firm's ability to act as a source of strength for its depository institution(s). These activities typically include continuous monitoring, targeted topical examinations, coordinated reviews, and an annual roll-up assessment resulting in ratings for the three rating components. The focus, frequency, and intensity of supervisory activities are based on the firm's unique risk profile and, therefore, can vary among complex firms. The relevance of certain supervisory guidance also may vary among complex firms based on each firm's unique risk profile. Supervisory guidance targeted at smaller bank holding companies, for example, may be more relevant for complex supervised insurance organizations with limited inherent exposure to a certain risk.

Noncomplex: Noncomplex firms, due to their lower risk profile, require less supervisory oversight relative to complex firms. The supervisory activities for these firms occur primarily

[9] 12 U.S.C. 326; 12 CFR part 261.

[1] In this framework, a ''supervised insurance organization'' is a depository institution holding company that is an insurance underwriting company, or that has over 25 percent of its consolidated assets held by insurance underwriting subsidiaries, or has been otherwise designated as a supervised insurance organization by Federal Reserve staff.

[2] This could happen if a firm's risk profile changes significantly and typically follows a strategic change for the firm (a material acquisition, divestiture, or product offering change).

during an annual full-scope inspection resulting in the assignment of the three component ratings. The supervision of noncomplex firms relies more heavily on the reports and opinions of a firm's other relevant supervisors, although these firms are subject to continuous monitoring and coordinated reviews as appropriate. The focus and types of supervisory activities for noncomplex firms are also set based on the unique risks of each firm.

Factors considered when classifying a supervised insurance organization as either complex or noncomplex include the organization's quality and level of capital and liquidity, the size of its depository institution, the complexity of its organizational structure, the nature and extent of any unregulated and/or unsupervised activities, any international exposure,[3] its product and portfolio risks, ratings and opinions from its regulatory supervisors, and its potential interconnectedness with the broader financial system.

For supervised insurance organizations that are new to Federal Reserve supervision, the classification as complex or noncomplex is done and communicated during the application phase after initial discussions with the firm. The firm's risk profile, including the characteristics listed above, and the proposed classification are vetted and decided by staff at the relevant Reserve Bank and the Board. Large, well-established, and financially strong supervised insurance organization with relatively small depository institutions can be classified as noncomplex if Federal Reserve staff considers the corresponding level of supervisory oversight sufficient to accomplish its objectives. Although the risk profile is the primary basis for determining a firm's classification, a firm is automatically classified as complex if its depository institution's average assets exceed $100 billion.

2. Supervisory Expectations

Supervised insurance organizations are expected to operate in a safe and sound manner, to comply with all applicable laws and regulations, and to possess sufficient financial and operational strength to serve as a source of strength for their depository institution(s) through a range of stressful yet plausible conditions. The management and risk management practices necessary to meet these expectations will vary based on a firm's specific risk profile and will vary significantly between the smallest, least risky firms and the largest, riskiest firms. Guidance describing supervisory expectations for safe and sound practices can be found in Supervision & Regulation (SR) letters published by the Board and other supervisory material. Supervisory guidance most relevant to a specific supervised insurance organization is driven by the unique risk profile of the firm. The firm's risk profile is reassessed by the Federal Reserve annually. Federal Reserve examiners will inform the firm if different supervisory guidance becomes more relevant as a result of a material change to the firm's risk profile. This is typically only the result of a significant business decision, like an acquisition, divestiture, or change to the firm's product offering or asset portfolio. This section describes general safety and soundness expectations and how the Board has adapted its supervisory expectations to reflect the unique characteristics of supervised insurance organization. The section is organized using the three rating components for—Governance and Controls, Capital Management, and Liquidity Management.

a. Governance and Controls

The Governance and Controls rating is derived from an assessment of the effectiveness of a firm's (1) board and senior management effectiveness, and (2) independent risk management and controls. All firms are expected to align their strategic business objectives with their risk appetite and risk management capabilities; maintain effective and independent risk management and control functions including internal audit; promote compliance with laws and regulations; and remain a source of financial and managerial strength for their depository institution(s). When assessing governance and controls, Federal Reserve examiners consider a firm's risk management capabilities relative to its risk exposure within the following areas: Internal audit, credit risk, legal and compliance risk, market risk, model risk, and operational risk, including cybersecurity/information technology and third party risk.

Governance & Controls Expectations

- Despite differences in their business models and the products offered, insurance companies and banks are expected to have effective and sustainable systems of governance and controls to manage their respective risks. The G&C framework for a supervised insurance organization should:
  - Clearly define roles and responsibilities throughout the organization;
  - Include policies and procedures, limits, requirements for documenting decisions, and decision-making and accountability chains of command; and
  - Provide timely information about risk and corrective action for non-compliance or weak oversight, controls, and management.
- The Board expects the sophistication of the G&C framework to be commensurate with the size, complexity, and risk profile of the firm. As such, G&C expectations for complex firms will be higher than that for noncomplex firms but will also vary based on each firm's unique risk profile.
- The enhanced prudential standards rule under Regulation YY[4] is not applicable to supervised insurance organizations. Unlike large banking organizations, these firms are not required by regulation to maintain a risk committee that periodically reviews and approves the risk management policies of the firm's operations and oversees the operation of its risk management framework, nor are they required by regulation to have a chief risk officer. The Board expects supervised insurance organization to have a risk management and control framework that is commensurate with their structure, risk profile, complexity, activities, and size. For any chosen structure, the firm's board is expected to have the capacity, expertise, and sufficient information to discharge risk oversight and governance responsibilities in a safe and sound manner. The chief risk officer facilitates an enterprise-wide approach to the identification and management of all risks across the organization and while the designation of a chief risk officer is not required, most large insurance companies have found value in having an independent chief risk officer. The Board cautions boards that they may be susceptible to undue risk and responsibility without a truly independent chief risk officer, which may result in safety and soundness concerns, particularly with complex firms, for whom the Board may require the designation of an independent chief risk officer. Firms that do not have a designated chief risk officer should have sufficient compensating controls in place to ensure that the head of risk management has adequate independence and stature to provide effective challenge. Likewise, the Federal Reserve may require a firm's board to establish a risk committee if it is not clear that the current board

[3] Supervised insurance organizations designated by their Group-Wide Supervisor as an Internationally Active Insurance Group (IAIG) are classified as complex.

[4] 12 CFR part 252.

structure provides sufficient oversight of the firm's risk management framework and practices.

In Assigning a G&C Rating, Federal Reserve Examiners Evaluate

• *Board and Senior Management Effectiveness*—The firm's board is expected to exhibit certain attributes consistent with effectiveness, including: (i) Setting a clear, aligned, and consistent direction regarding the firm's strategy and risk appetite; (ii) directing senior management regarding board reporting; (iii) overseeing and holding senior management accountable; (iv) supporting the independence and stature of independent risk management and internal audit; and (v) maintaining a capable board and an effective governance structure. As the consolidated supervisor, the Board focuses on the board of the supervised insurance organization and its committees. Complex firms are expected to take into consideration the Board's guidance on board of directors' effectiveness.[5] In assessing the effectiveness of a firm's senior management, Federal Reserve examiners consider the extent to which senior management effectively and prudently manages the day-to-day operations of the firm and provides for ongoing resiliency; implements the firm's strategy and risk appetite; identifies and manages risks; maintains an effective risk management framework and system of internal controls; and promotes prudent risk taking behaviors and business practices, including compliance with laws and regulations such as those related to consumer protection and the Bank Secrecy Act/Anti-Money Laundering and Office of Foreign Assets Control (BSA/AML and OFAC). Federal Reserve examiners evaluate how the framework allows management to be responsible for and manage all risk types, including emerging risks, within the business lines. Examiners rely to the fullest extent possible on insurance and bank supervisors' examination reports and information concerning risk and management in specific lines of business, including relying specifically on state insurance regulators to evaluate and assess how firms manage the pricing, underwriting, and reserving risk of their insurance operations.

• *Independent Risk Management and Controls*—In assessing a firm's independent risk management and controls, Federal Reserve examiners consider the extent to which independent risk management effectively evaluates whether the firm's risk appetite framework identifies and measures all of the firm's risks; establishes appropriate risk limits; and aggregates, assesses and reports on the firm's risk profile and positions. Additionally, the firm is expected to demonstrate that its internal controls are appropriate and tested for effectiveness and sustainability.

• *Internal Audit* is an integral part of a supervised insurance organization's internal control system and risk management structure. An effective internal audit function plays an essential role by providing an independent risk assessment and objective evaluation of all key governance, risk management, and internal control processes. Internal audit is expected to effectively and independently assess the firm's risk management framework and internal control systems, and report findings to senior management and to the firm's audit committee. Despite differences in business models, the Board expects the largest, most complex supervised insurance organizations to have internal audit practices in place that are similar to those at banking organizations and as such, no modification to existing guidance is required for these firms.[6] At the same time, the Board recognizes that firms should have an internal audit function that is appropriate to their size, nature, and scope of activities. Therefore, for noncomplex firms, Federal Reserve examiners will use the expectations in the insurance company's domicile state's Annual Financial Reporting Regulation (NAIC Model Audit Rule 205), or similar state regulation, to assess the effectiveness of a firm's internal audit function.

The principles of sound risk management described in the previous sections apply to the entire spectrum of risk management activities of a supervised insurance organization, including but not limited to:

• *Credit risk,* which arises from the possibility that a borrower or counterparty will fail to perform on an obligation. Fixed income securities, by far the largest asset class for insurance companies, is the largest source of credit risk. This is unlike banks, where loans generally make up the largest portion of balance sheet assets. Life insurer investment portfolios in particular are generally characterized by longer duration holdings compared to those of banks. Additionally, an insurance company's reinsurance recoverables/receivables arising from the use of third-party reinsurance and participation in regulatory required risk-pooling arrangements expose the firm to additional counterparty credit risk. The Federal Reserve will scope examination work based on a firm's level of inherent credit risk. The level of inherent risk will be determined by analyzing the composition, concentration, and quality of the consolidated investment portfolio; the amount of a firm's reinsurance recoverables and the credit quality of the individual reinsurers; and credit exposures associated with derivatives, securities lending, or other activities that may also have off-balance sheet counterparty credit exposures. In determining the effectiveness of a firm's management of its credit risk, Federal Reserve examiners will rely, where possible, on the assessments made by other relevant supervisors for the bank and the insurance companies. In its own assessment, the Federal Reserve will determine whether the board and senior management have established an appropriate credit risk governance framework consistent with the firm's risk appetite; whether policies, procedures and limits are adequate and provide for ongoing monitoring, reporting and control of credit risk; the adequacy of management information systems as it relates to credit risk; and the sufficiency of internal audit and independent review coverage of credit risk exposure.

• *Market risk,* which arises from exposures to movements in market prices as a result of underlying changes in, for example, interest rates, equity prices, foreign exchange rates, commodity prices, or real estate prices. The Federal Reserve will scope examination work based on a firm's level of inherent market risk exposure, which is normally driven by the primary business line(s) in which the firm is engaged as well as the structure of the investment portfolio. While interest rate risk (IRR) differs between insurance companies and banks, the degree of IRR also differs based on the type of insurance products the firm offers. IRR is a more significant risk factor for life insurers than for property/casualty (P/C) insurers since life and annuity products are often spread-based, longer in duration, may include

[5] SR 21–3: Supervisory Guidance on Board of Directors' Effectiveness, *https://www.federalreserve.gov/supervisionreg/srletters/SR2103.htm.*

[6] Regulatory guidance provided in SR 03–05 *Amended Interagency Guidance on the Internal Audit Function and its Outsourcing, https://www.federalreserve.gov/boarddocs/srletters/2003/sr0305.htm* and SR 13–1 *Supplemental Policy Statement on the Internal Audit Function and Its Outsourcing, https://www.federalreserve.gov/supervisionreg/srletters/sr1301.htm,* are applicable to complex supervised insurance organizations only.

embedded product guarantees, and can pose disintermediation risk. P/C insurers, especially property insurers, generally offer short-term contracts with the potential for frequent re-pricing, are subject to much less disintermediation risk. A firm may be exposed to inherent market risk due to its investment portfolio or as result of its product offerings, including variable and indexed life insurance and annuity products, or asset/wealth management business. Generally foreign exchange and commodity risk is low for supervised insurance organizations but could exist for some complex firms. Firms are expected to have sound risk management infrastructure that adequately identifies, measures, monitors, and controls any material or significant forms of inherent market risks to which it is exposed.

• *Model risk* is the potential for adverse consequences from decisions based on incorrect or misused model outputs and reports. Model risk can lead to financial loss, poor business and strategic decision-making, or damage to a firm's reputation. Supervised insurance organizations are often heavily reliant on models for product pricing and reserving, risk and capital management, strategic planning and other decision-making purposes. A sound model risk management framework helps manage this risk.[7] Federal Reserve examiners will take into account the firm's size, nature, and complexity, as well as the extent of use and sophistication of its models when assessing its model risk management program. Examiners focus on the governance framework, policies and controls, and aggregated model risk management through a holistic evaluation of the firm's practices. The Federal Reserve's review of a firm's model risk management program complements the work of the firm's other relevant supervisors. A sound model risk management framework includes three main elements: (1) An accurate model inventory and an appropriate approach to model development, implementation, and use; (2) effective model validation and continuous model performance monitoring; and (3) a strong governance framework that provides explicit support and structure for model risk management through policies defining relevant activities, procedures that implement those policies, allocation of resources, and mechanisms for evaluating whether policies and procedures are being carried out as specified, including internal audit review. The Federal Reserve will rely on work already conducted by other relevant supervisors and appropriately collaborate with the state insurance regulators on their findings related to insurance models. With respect to the business of insurance, Federal Reserve examiners focus on the firm's adherence to its own policies and procedures and the comprehensiveness of model validation rather than technical specifications such as the appropriateness of the model, its assumptions or output. The Federal Reserve may request that firms provide model documentation or model validation reports for insurance and bank models when performing transaction testing.

• *Legal risk* arises from the potential that unenforceable contracts, lawsuits, or adverse judgments can disrupt or otherwise negatively affect the operations or financial condition of a supervised insurance organization. *Compliance risk* is the risk of regulatory sanctions, fines, penalties or losses resulting from failure to comply with laws, rules, regulations, or other supervisory requirements applicable to a firm. By offering multiple financial service products that may include insurance, annuity, banking, services provided by securities broker-dealers, and asset and wealth management products, provided through a diverse distribution network, supervised insurance organizations are inherently exposed to a significant amount of legal and compliance risk. As the consolidated supervisor, the Board expects firms to have an enterprise-wide legal and compliance risk management program that covers all business lines, legal entities, and jurisdictions of operation. Firms are expected to have compliance risk management governance, oversight, monitoring, testing, and reporting commensurate with their size and complexity, and to ensure compliance with applicable laws and regulations. The principles-based guidance in existing SR letters related to legal and compliance risk is applicable to supervised insurance organizations.[8] For both complex and noncomplex firms, Federal Reserve examiners rely on the work of the firm's other supervisors. As described in section C, Incorporating the Work of Other Supervisors, the opinions, examination results, ratings, supervisory issues, and enforcement actions from other supervisors will be incorporated into a consolidated assessment of the enterprise-wide legal and compliance risk management framework.

○ Money laundering, terrorist financing and other illicit financial activity risk is the risk of providing criminals access to the legitimate financial system and thereby being used to facilitate financial crime. This financial crime includes laundering criminal proceeds, financing terrorism, and conducting other illegal activities. Money laundering and terrorist financing risk is associated with a financial institution's products, services, customers, and geographic locations. This and other illicit financial activity risks can impact a firm across business lines, legal entities, and jurisdictions. A reasonably designed compliance program generally includes a structure and oversight that mitigates these risks and supports regulatory compliance with both Bank Secrecy Act/Anti-Money Laundering (BSA/AML) and Office of Foreign Assets Control (OFAC) requirements. Although OFAC regulations are not part of the BSA, OFAC compliance programs are frequently assessed in conjunction with BSA/AML. Supervised insurance organizations are not defined as financial institutions under the BSA and, therefore, are not required to have an AML program, unless the firm is directly selling certain insurance products. However, certain subsidiaries and affiliates of supervised insurance organizations, such as insurance companies and banks, are defined as financial institutions under 31 U.S.C. 5312(a)(2) and must develop and implement a written BSA/AML compliance program as well as comply with other BSA regulatory requirements. Unlike banks, insurance companies' BSA/AML obligations are limited to certain products, referred to as covered insurance products.[9] The volume of

[7] SR 11–7 *Guidance on Model Risk Management* is applicable to supervised insurance organizations.

[8] SR 08–8 *Compliance Risk Management Programs and Oversight at Large Banking Organizations with Complex Compliance Profiles, https://www.federalreserve.gov/boarddocs/srletters/2008/SR0808.htm,* is applicable to complex supervised insurance organizations. For noncomplex firms, the Federal Reserve will assess legal and compliance risk management based on the guidance in SR 16–11 *Supervisory Guidance for Assessing Risk Management at Supervised Institutions with Total Consolidated Assets Less than $50 Billion, https://www.federalreserve.gov/supervisionreg/srletters/sr1611.htm.*

[9] ''Covered products'' means: A permanent life insurance policy, other than a group life insurance policy; an annuity contract, other than a group annuity contract; or any other insurance product with features of cash value or investment.

''Permanent life insurance policy'' means an agreement that contains a cash value or investment element and that obligates the insurer to indemnify or to confer a benefit upon the insured or beneficiary to the agreement contingent upon the death of the insured. ''Annuity contract'' means any agreement between the insurer and the contract

Continued

covered products, which the Financial Crimes Enforcement Network (FinCEN) has determined to be of higher risk, is an important driver of supervisory focus. In addition, as U.S. persons, all supervised insurance organizations (including their subsidiaries and affiliates) are subject to Office of Foreign Assets Control (OFAC) regulations. Federal Reserve examiners assess all material risks that each firm faces, extending to whether business activities across the consolidated organization, including within its individual subsidiaries or affiliates, comply with the legal requirements of BSA and OFAC regulations. In keeping with the principles of a risk-based framework and proportionality, Federal Reserve supervision for BSA/AML and OFAC primarily focuses on oversight of compliance programs at a consolidated level and relies on work by other relevant supervisors to the fullest extent possible. In the evaluation of a firm's risks and BSA/AML and OFAC compliance program, however, it may be necessary for examiners to review compliance with BSA/AML and OFAC requirements at individual subsidiaries or affiliates in order to fully assess material risks of the supervised insurance organization.

- *Operational risk* is the risk of loss resulting from inadequate or failed internal processes, people, and systems, or from external events. Operational resilience is the ability to maintain operations, including critical operations and core business lines, through a disruption from any hazard. It is the outcome of effective operational risk management combined with sufficient financial and operational resources to prepare, adapt, withstand, and recover from disruptions. A firm that operates in a safe and sound manner is able to identify threats, respond and adapt to incidents, and recover and learn from such threats and incidents so that it can prioritize and maintain critical operations and core business lines, along with other operations, services and functions identified by the firm, through a disruption.

  - *Cybersecurity/information technology risks* are a subset of operational risk and arise from operations of a firm requiring a strong and robust internal control system and risk management oversight structure. Information Technology (IT) and Cybersecurity (Cyber) functions are especially critical to firms' operations. Examiners of financial institutions, including supervised insurance organizations, find detailed guidance on mitigating these risks in the Federal Financial Institutions Examination Council's (FFIEC) IT Handbooks. In assessing IT/Cyber risks, Federal Reserve examiners will assess a firm's board and senior management for effective oversight and support of IT management; information/cyber security program for strong board and senior management support, integration of security activities and controls through business processes, and establishment of clear accountability for security responsibilities; IT operations for sufficient personnel, system capacity and availability, and storage capacity adequacy to achieve strategic objectives and appropriate solutions: Development and acquisition processes' ability to identify, acquire, develop, install, and maintain effective IT to support business operations; and appropriate business continuity management processes to effectively oversee and implement resilience, continuity, and response capabilities to safeguard employees, customers, assets, products, and services. Complex and noncomplex firms will be assessed in these areas. All supervised insurance organizations are expected to notify the Federal Reserve of any security breaches involving sensitive customer information, whether or not the institution notifies its customers.[10]

  - *Third party risk* is also a subset of operational risk and arises from a firm's use of service providers to perform operational or service functions. These risks may be inherent to the outsourced activity or be introduced with the involvement of the service provider. When assessing effective third party risk management, Federal Reserve examiners will evaluate eight areas: (1) Third party risk management governance, (2) risk assessment framework, (3) due diligence in the selection of a service provider, (4) a review of any incentive compensation embedded in a service provider contract, (5) management of any contract or legal issues arising from third party agreements, (6) ongoing monitoring and reporting of third parties, (7) business continuity and contingency of the third party for any service disruptions, and (8) effective internal audit program to assess the risk and controls of the firm's third party risk management program.[11]

b. Capital Management

The Capital Management rating is derived from an assessment of a firm's current and stressed level of capitalization, and the quality of its capital planning and stress testing. A capital management program should be commensurate with a supervised insurance organization's complexity and unique risk profile. In assigning this rating, the Federal Reserve evaluates the extent to which a firm maintains sound capital planning practices through effective governance and oversight, effective risk management and controls, maintenance of updated capital policies and contingency plans for addressing potential shortfalls, and incorporation of appropriately stressful conditions into capital planning and projections of capital positions. The extent to which a firm's capital is sufficient to comply with regulatory requirements, to support the firm's ability to meet its obligations, and to enable the firm to remain a source of strength to its depository institution(s) in a range of stressful, but plausible, economic and financial environments is also evaluated.

Insurance company balance sheets are typically quite different from those of most banking organizations. For insurance companies, investment strategies focus on cash flow matching to reduce interest rate risk and provide liquidity to support their liabilities, while for traditional banks, deposits (liabilities) are attracted to support investment strategies. Additionally, for insurers, capital provides a buffer for policyholder claims and creditor obligations, helping the firm absorb adverse deviations in expected claims experience, and other drivers of economic loss. The Board recognizes that the capital needs for insurance activities are materially different from those of banking activities. Insurers also often face capital fungibility constraints not faced by banks.

In assessing a supervised insurance organization's capital management, the Federal Reserve relies to the fullest extent possible on information provided by the state insurance regulators, including the firm's ORSA and the state insurance regulator's written assessment of the ORSA. An ORSA is an internal process undertaken by an insurance group to assess the adequacy of its risk management and current and prospective capital position under normal and severe stress scenarios. As part of the ORSA, insurance groups are required to analyze all reasonably foreseeable and relevant material risks

owner whereby the insurer promises to pay out a fixed or variable income stream for a period of time.

[10] SR 05–23, Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice, applies to all supervised insurance organizations.

[11] *SR Letter 13–19, Guidance on Managing Outsourcing Risk, https://www.federalreserve.gov/supervisionreg/srletters/sr1319.htm,* applies to complex and noncomplex supervised insurance organizations.

that could have an impact on their ability to meet obligations.

The Board expects supervised insurance organizations to have sound governance over their capital planning process.[12] A firm should establish capital goals that are approved by the board of directors, and that reflect the potential impact of legal and/or regulatory restrictions on the transfer of capital between legal entities. In general, senior management should establish the capital planning process, which should be reviewed and approved periodically by the board. The board should require senior management to provide clear, accurate, and timely information on the firm's material risks and exposures to inform board decisions on capital adequacy and actions. The capital planning process should clearly reflect the difference between the risk profiles and associated capital needs of the insurance and banking businesses.

A firm should have a risk management framework that appropriately identifies, measures, and assesses material risks and provides a strong foundation for capital planning. This framework should be supported by comprehensive policies and procedures, clear and well-established roles and responsibilities, strong internal controls, and effective reporting to senior management and the board. In addition, the risk management framework should be built upon sound management information systems.

As part of capital management, a firm should have a sound internal control framework that helps ensure that all aspects of the capital planning process are functioning as designed and result in accurate assessments of the firm's capital needs. The framework should include an independent internal audit function as well as other review functions with appropriate staff expertise, experience, and stature in the organization to monitor the adequacy of capital risk measurement and management processes.

The governance and oversight framework should include a written assessment of the principles and guidelines used for capital planning, issuance, and usage, including internal post-stress capital goals and targeted capital levels; guidelines for dividend payments and stock repurchases; strategies for addressing capital shortfalls; and internal governance responsibilities and procedures for the capital policy. The capital policy should reflect the unique capital needs of the insurance and banking businesses based on their risks, be approved by the firm's board of directors or a designated committee of the board, and be re-evaluated periodically and revised as necessary.

A strong capital management program will incorporate appropriately stressful conditions and events that could adversely affect the firm's capital adequacy and capital planning. As part of its capital plan, a firm should use at least one scenario that stresses the specific vulnerabilities of the firm's activities and associated risks, including those related to the firm's insurance activities and its banking activities.

Supervised insurance organizations should employ estimation approaches that allow them to project the impact on capital positions of various types of stressful conditions and events, and that are independently validated. A firm should estimate losses, revenues, expenses, and capital using a sound method that incorporates macroeconomic and other risk drivers. The robustness of a firm's capital stress testing processes should be commensurate with the to its capital position.

c. Liquidity Management

The Liquidity Management rating is derived from an assessment of the supervised insurance organization's liquidity position and the quality of its liquidity risk management program. Each firm's liquidity risk management program should be commensurate with its complexity and unique risk profile.

The Board recognizes that insurance companies are typically less exposed to traditional liquidity risk than are banks. Traditional banking activity involves a liquidity transformation of liquid demand deposits into an asset on a banking organization's balance sheet, notably from the perspective of liquidity risk, illiquid bank loans. In traditional insurance business, the fact that an occurrence of an insured event is required for a claim payment, helps reduce liquidity risk. Insurers minimize liquidity risk by attempting to match expected asset cash flows against expected claims payments. The Board's expectations for supervised insurance organizations recognize and reflect this difference in inherent liquidity risk.

The Board, however, does expect all depository institution holding companies, including supervised insurance organizations, to adhere to basic principles for managing liquidity risk.[13]

The Federal Reserve's supervision of supervised insurance organizations focuses on the sections of SR 10–6 that are most relevant to the liquidity characteristics of these firms. For example, guidance on intra-day liquidity management would only be applicable for supervised insurance organizations with material intra-day liquidity risks. Additionally, specific references to liquid assets in SR 10–6 may be more broadly interpreted to include other asset classes such as certain investment-grade corporate bonds.

The intensity of the Federal Reserve's supervisory focus on liquidity risk is influenced by each firm's individual risk profile. Traditional property and casualty insurance products are typically short duration liabilities backed by short-duration, liquid assets. Because of this, they typically present less liquidity risk than traditional banking products. However, some non-traditional life insurance and retirement products create liquidity risk through features that allow payments at the request of policyholders without the occurrence of an insured event. Risks of certain other insurance products are often mitigated using derivatives. Any differences between collateral requirements related to hedging and the related liability cash flows can also create liquidity risk. The Board expects firms significantly engaged in these types of insurance activities to have correspondingly more sophisticated liquidity risk management programs.

A strong liquidity risk management program includes comprehensive cash flow forecasting with appropriate granularity, preferably for each major legal entity as well as for the consolidated enterprise. The firm's suite of quantitative metrics should effectively inform senior management and the board of directors of the firm's unique liquidity risk profile and identify liquidity events or stresses that could detrimentally affect the firm. The metrics used to measure a firm's liquidity position may vary by type of business.

Federal Reserve examiners rely to the fullest extent possible on each firm's ORSA, which requires all firms to include a discussion of the risk management framework and assessment

[12] SR 15–19: *Federal Reserve Supervisory Assessment of Capital Planning and Positions for Firms Subject to Category II and III Standards, https://www.federalreserve.gov/supervisionreg/srletters/sr1519.htm,* is applicable to complex supervised insurance organizations, however, Federal Reserve focuses on the sections most relevant for these firms. For example, references to pre-provision net revenue (PPNR) modeling and risk-weighted asset (RWA) projections are not applicable to supervised insurance organizations.

[13] For an explanation of these principles, see SR Letter 10–6, *Interagency Policy Statement on Funding and Liquidity Risk Management, https://www.federalreserve.gov/boarddocs/srletters/2010/sr1006.htm.*

of material risks, including liquidity risk.

Supervised insurance organizations are expected to perform liquidity stress testing at least annually and more frequently if necessary, based on their risk profile. The scenarios used should reflect the firm's specific risk profile and include both idiosyncratic and system-wide stress events. Stress testing should inform the firm on the amount of liquid assets necessary to meet net cash outflows over relevant time periods, including at least a one-year time horizon. Firms should hold a liquidity buffer comprised of highly liquid assets to meet stressed net cash outflows. The liquidity buffer should be measured using appropriate haircuts based on asset quality, duration, and expected market illiquidity based on the stress scenario assumptions. Stress testing should reflect the expected impact on collateral requirements.

Fungibility of liquidity is often limited between an insurance group's legal entities. Large insurance groups can operate with a significant number of legal entities and many different regulatory and operational barriers to transferring funds among them. Regulations designed to protect policyholders of insurance operating companies can limit the transferability of funds from an insurance company to other legal entities within the group, including to other insurance operating companies. Supervised insurance organizations should carefully consider these limitations in their stress testing and liquidity risk management framework. Effective liquidity stress testing should include stress testing at the legal entity level with consideration for intercompany liquidity fungibility. Furthermore, the firm should be able to measure and provide an assessment of liquidity at the top-tier depository institution holding company in a manner that incorporates fungibility constraints.

The enterprise-wide governance and oversight framework should be consistent with the firm's liquidity risk profile and include policies and procedures on liquidity risk management. Policies and procedures should detail the oversight of liquidity risk through a specific document such as a Liquidity Policy. Policies and procedures should include the frequency of liquidity reporting and stress testing. Stress testing results should be communicated clearly and regularly to senior management and the board. A comprehensive contingency funding plan, commensurate with the firm's categorization and liquidity risk profile, should be maintained to manage liquidity stress events. The contingency funding plan should detail specific policies, procedures, and actions for addressing liquidity stress events or breaches of liquidity risk limits.

Supervised insurance organizations should also have an enterprise-wide approach for the control and oversight of liquidity risk. This should include management committee reporting of liquidity risk, governance, and assumptions for key elements of liquidity risk management such as stress testing and the firm's liquidity risk appetite, among others. The risk appetite statement, which should be approved by the board of directors, should detail and define the level of impact of a liquidity event or stress that the firm can. Additionally, the governance framework should detail the process and policies around liquidity risk identification, measurement, and risk-mitigating actions.

B. Supervisory Ratings

Supervised insurance organizations are expected to operate in a safe and sound manner, to comply with all applicable laws and regulations, and to possess sufficient financial and operational strength to serve as a source of strength for their depository institution(s) through a range of stressful yet plausible conditions. Supervisory ratings and supervisory findings are used to communicate the assessment of a firm. Each year, the Federal Reserve examiners assign one of four ratings to each of the three rating components used to assess supervised insurance organizations. The rating components are Capital Management, Liquidity Management, and Governance & Controls. The four potential ratings are Broadly Meets Expectations, Conditionally Meets Expectations, Deficient-1, and Deficient-2. To be considered ''well managed,'' a firm must receive a rating of Conditionally Meets Expectations or better in each of the three rating components. Each rating is defined specifically for supervised insurance organizations with particular emphasis on the obligation that firms serve as a source of financial and managerial strength for their depository institution(s). High-level definitions for each rating are below, followed by more specific rating definitions for each component.

Broadly Meets Expectations: The supervised insurance organization's practices and capabilities broadly meet supervisory expectations. The holding company effectively serves as a source of managerial and financial strength for its depository institution(s) and possesses sufficient financial and operational strength and resilience to maintain safe-and-sound operations through a range of stressful yet plausible conditions. The firm may have outstanding supervisory issues requiring corrective actions, but these are unlikely to present a threat to its ability to maintain safe-and-sound operations and unlikely to negatively impact its ability to fulfill its obligation to serve as a source of strength for its depository institution(s). These issues are also expected to be corrected on a timely basis during the normal course of business.

Conditionally Meets Expectations: The supervised insurance organization's practices and capabilities are generally considered sound. However, certain supervisory issues are sufficiently material that if not resolved in a timely manner during the normal course of business, may put the firm's prospects for remaining safe and sound, and/or the holding company's ability to serve as a source of managerial and financial strength for its depository institution(s), at risk. A firm rated ''Conditionally Meets Expectations'' has the ability, resources, and management capacity to resolve its issues and has developed a sound plan to address the issue(s) in a timely manner. Examiners will work with the firm to develop an appropriate timeframe during which it will be required to resolve that supervisory issue(s) leading to this rating.

Deficient-1: Financial or operational deficiencies in a supervised insurance organization's practices or capabilities put its prospects for remaining safe and sound, and/or the holding company's ability to serve as a source of managerial and financial strength for its depository institution(s), at significant risk. The firm is unable to remediate these deficiencies in the normal course of business, and remediation would typically require it to make material changes to its business model or financial profile, or its practices or capabilities. A firm with a Deficient-1 rating is required to take timely action to correct financial or operational deficiencies and to restore and maintain its safety and soundness and compliance with laws and regulation. Supervisory issues that place the firm's safety and soundness at significant risk, and where resolution is likely to require steps that clearly go beyond the normal course of business—such as issues requiring a material change to the firm's business model or financial profile, or its governance, risk management or internal control structures or practices—would generally warrant assignment of a Deficient-1 rating. There is a strong presumption that a firm with a

Deficient-1 rating will be subject to an enforcement action.

Deficient-2: Financial or operational deficiencies in a supervised insurance organization's practices or capabilities present a threat to its safety and soundness, have already put it in an unsafe and unsound condition, and/or make it unlikely that the holding company will be able to serve as a source of financial and managerial strength to its depository institution(s). A firm with a Deficient-2 rating is required to immediately implement comprehensive corrective measures and demonstrate the sufficiency of contingency planning in the event of further deterioration. There is a strong presumption that a firm with a Deficient-2 rating will be subject to a formal enforcement action.

Definitions for the Capital Management Component Rating

Broadly Meets Expectations: Despite the potential existence of outstanding supervisory issues, the supervised insurance organization's capital management broadly meets supervisory expectations, supports maintenance of safe-and-sound operations, and supports the holding company's ability to serve as a source of financial strength for its depository institution(s). Specifically:

- The firm's current and projected capital positions on a consolidated basis and within each of its material business lines/legal entities comply with regulatory requirements and support its ability to absorb potential losses, meet obligations, and continue to serve as a source of financial strength for its depository institution(s);
- Capital management processes are sufficient to give credibility to stress testing results and the firm is capable of producing sound assessments of capital adequacy through a range of stressful yet plausible conditions; and
- Potential capital fungibility issues are effectively mitigated, and capital contingency plans allow the holding company to continue to act as a source of financial strength for its depository institution(s) through a range of stressful yet plausible conditions.

Conditionally Meets Expectations: Capital adequacy meets regulatory minimums, both currently and on a prospective basis. Supervisory issues exist but these do not threaten the holding company's ability to act as a source of financial strength for its depository institution(s) through a range of stressful yet plausible conditions. Specifically, if left unresolved, these issues:

- May threaten the firm's ability to produce sound assessments of capital adequacy through a range of stressful yet plausible conditions; and/or
- May result in the firm's projected capital positions being insufficient to absorb potential losses, comply with regulatory requirements, and support the holding company's ability to meet current and prospective obligations and continue to serve as a source of financial strength to its depository institution(s).

Deficient-1: Financial or operational deficiencies in a supervised insurance organization's capital management put its prospects for remaining safe and sound through a range of plausible conditions at significant risk. The firm is unable to remediate these deficiencies in the normal course of business, and remediation would typically require a material change to the firm's business model or financial profile, or its capital management processes.

Examples of issues that may result in a Deficient-1 rating include, but are not limited to:

- Capital adequacy currently meets regulatory minimums although there may be uncertainty regarding the firm's ability to continue meeting regulatory minimums.
- Fungibility concerns may exist that could challenge the firm's ability to contribute capital to its depository institutions under certain stressful yet plausible scenarios.
- Supervisory issues may exist that undermine the credibility of the firm's current capital adequacy and/or its stress testing results.

Deficient-2: Financial or operational deficiencies in a supervised insurance organization's capital management present a threat to the firm's safety and soundness, a threat to the holding company's ability to serve a source of financial strength for its depository institution(s), or have already put the firm in an unsafe and unsound condition.

Examples of issues that may result in a Deficient-2 rating include, but are not limited to:

- Capital adequacy may currently fail to meet regulatory minimums or there is significant concern that the firm will not meet capital adequacy minimums prospectively.
- Supervisory issues may exist that significantly undermine the firm's capital adequacy metrics either currently or prospectively.
- Significant fungibility constraints may exist that would prevent the holding company from contributing capital to its depository institution(s) and fulfilling its obligation to serve as a source of financial strength.
- The holding company may have failed to act as source of financial strength for its depository institution when needed.

Definitions for the Liquidity Management Component Rating

Broadly Meets Expectations: Despite the potential existence of outstanding supervisory issues, the supervised insurance organization's liquidity management broadly meets supervisory expectations, supports maintenance of safe-and-sound operations, and supports the holding company's ability to serve as a source of financial strength for its depository institutions(s). The firm generates sufficient liquidity to meet its short-term and long-term obligations currently and under a range of stressful yet plausible conditions. The firm's liquidity management processes, including its liquidity contingency planning, support its obligation to act as a source of financial strength for its depository institution(s). Specifically:

- The firm is capable of producing sound assessments of liquidity adequacy through a range of stressful yet plausible conditions; and
- The firm's current and projected liquidity positions on a consolidated basis and within each of its material business lines/legal entities comply with regulatory requirements and support the holding company's ability to meet obligations and to continue to serve as a source of financial strength for its depository institution(s).

Conditionally Meets Expectations: Certain material financial or operational weaknesses in a supervised insurance organization's liquidity management place its prospects for remaining safe and sound through a range of stressful yet plausible conditions at risk if not resolved in a timely manner during the normal course of business.

Specifically, if left unresolved, these weaknesses:

- May threaten the firm's ability to produce sound assessments of liquidity adequacy through a range of conditions; and/or
- May result in the firm's projected liquidity positions being insufficient to comply with regulatory requirements and support the firm's ability to meet current and prospective obligations and to continue to serve as a source of financial strength to its depository institution(s).

Deficient-1: Financial or operational deficiencies in a supervised insurance organization's liquidity management put the firm's prospects for remaining safe and sound through a range of stressful yet plausible conditions at significant risk. The firm is unable to remediate these deficiencies in the normal course of business, and remediation would

typically require a material change to the firm's business model or financial profile, or its liquidity management processes.

Examples of issues that may result in a Deficient-1 rating include, but are not limited to:

- The firm is currently able to meet its obligations but there may be uncertainty regarding the firm's ability to do so prospectively.
- The holding company's liquidity contingency plan may be insufficient to support its obligation to act as a source of financial strength for its depository institution(s).
- Supervisory issues may exist that undermine the credibility of the firm's liquidity metrics and stress testing results.

Deficient-2: Financial or operational deficiencies in a supervised insurance organization's liquidity management present a threat to its safety and soundness, a threat to the holding company's ability to serve as a source of financial strength for its depository institution(s), or have already put the firm in an unsafe and unsound condition.

Examples of issues that may result in a Deficient-2 rating include, but are not limited to:

- Liquidity shortfalls may exist within the firm that have prevented the firm, or are expected to prevent the firm, from fulfilling its obligations, including the holding company's obligation to act as a source of financial strength for its depository institution(s).
- Liquidity adequacy may currently fail to meet regulatory minimums or there is significant concern that the firm will not meet liquidity adequacy minimums prospectively for at least one of its regulated subsidiaries.
- Supervisory issues may exist that significantly undermine the firm's liquidity metrics either currently or prospectively.
- Significant fungibility constraints may exist that would prevent the holding company from supporting its depository institution(s) and fulfilling its obligation to serve as a source of financial strength.
- The holding company may have failed to act as source of financial strength for its depository institution when needed.

Definitions for the Governance and Controls Component Rating

Broadly Meets Expectations: Despite the potential existence of outstanding supervisory issues, the supervised insurance organization's governance and controls broadly meet supervisory expectations, supports maintenance of safe-and-sound operations, and supports the holding company's ability to serve as a source of financial and managerial strength for its depository institutions(s). Specifically, the firm's practices and capabilities are sufficient to align strategic business objectives with its risk appetite and risk management capabilities, maintain effective and independent risk management and control functions, including internal audit; promote compliance with laws and regulations; and otherwise provide for the firm's ongoing financial and operational resiliency through a range of conditions. The firm's governance and controls clearly reflect the holding company's obligation to act as a source of financial and managerial strength for its depository institution(s).

Conditionally Meets Expectations: Certain material financial or operational weaknesses in a supervised insurance organization's governance and controls practices may place the firm's prospects for remaining safe and sound through a range of conditions at risk if not resolved in a timely manner during the normal course of business. Specifically, if left unresolved, these weaknesses may threaten the firm's ability to align strategic business objectives with its risk appetite and risk-management capabilities; maintain effective and independent risk management and control functions, including internal audit; promote compliance with laws and regulations; or otherwise provide for the firm's ongoing resiliency through a range of conditions. Supervisory issues may exist related to the firm's internal audit function, but internal audit is still regarded as effective.

Deficient-1: Deficiencies in a supervised insurance organization's governance and controls put its prospects for remaining safe and sound through a range of conditions at significant risk. The firm is unable to remediate these deficiencies in the normal course of business, and remediation would typically require a material change to the firm's business model or financial profile, or its governance, risk management or internal control structures or practices.

Examples of issues that may result in a Deficient-1 rating include, but are not limited to:

- The firm may be currently subject to, or expected to be subject to, informal or formal enforcement action(s) by the Federal Reserve or another regulator tied to violations of laws and regulations.
- Significant legal issues may have or be expected to impede the holding company's ability to act as a source of financial strength for its depository institution(s).
- The firm may have engaged in intentional misconduct.
- Deficiencies within the firm's governance and controls may limit the credibility of the firm's financial results, limit the board or senior management's ability to make sound decisions, or materially increase the firm's risk of litigation.
- The firm's internal audit function may be considered ineffective.
- Deficiencies in the firm's governance and controls may have limited the holding company's ability to act as a source of financial and/or managerial strength for its depository institution(s).

Deficient-2: Financial or operational deficiencies in a supervised insurance organization's governance and controls present a threat to its safety and soundness, a threat to the holding company's ability to serve as a source of financial strength for its depository institution(s), or have already put the firm in an unsafe and unsound condition.

Examples of issues that may result in a Deficient-2 rating include, but are not limited to:

- The firm is currently subject to, or expected to be subject to, formal enforcement action(s) by the Federal Reserve or another regulator tied to violations of laws and regulations.
- Significant legal issues may be impeding the holding company's ability to act as a source of financial strength for its depository institution(s).
- The firm may have engaged in intentional misconduct.
- The holding company may have failed to act as a source of financial and/or managerial strength for its depository institution(s) when needed.
- The firm's internal audit function is regarded as ineffective.

C. Incorporating the Work of Other Supervisors

Similar to the approach taken by the Federal Reserve in its consolidated supervision of other firms, the supervision of supervised insurance organizations relies, to the fullest extent possible, on work done by other relevant supervisors. The Federal Reserve collaboratively coordinates with, communicates with, and leverages the work of the Office of the Comptroller of the Currency (OCC), Federal Deposit Insurance Corporation (FDIC), Financial Crimes Enforcement Network (FinCEN), Internal Revenue Service (IRS), applicable state insurance regulators, and other relevant supervisors to achieve its supervisory

objectives and eliminate unnecessary burden.

Existing statutes specifically require the Board to coordinate with, and to rely to the fullest extent possible on work by the state insurance regulators. The Board and all state insurance regulators have entered into Memorandums of Understanding (MOU) allowing supervisors to freely exchange information relevant for the effective supervision of supervised insurance organizations. Federal Reserve examiners take the actions below with respect to state insurance regulators to support accomplishing the objective of minimizing supervisory duplication and burden, without sacrificing effective oversight:

- Routine discussions with state insurance regulatory staff with greater frequency during times of stress;
- Discussions around the annual supervisory plan, including how best to leverage work done by the state and potential participation by state insurance regulatory staff on relevant supervisory activities;
- Consideration of the opinions and work done by the state when scoping relevant examination activities;
- Documenting any input received from the state and consideration given to the opinions and work done by the state for relevant supervisory activities;
- Sharing and discussing with the state the annual ratings and relevant conclusion documents from supervisory activities;
- Collaboratively working with the states and the National Association of Insurance Commissioners (NAIC) on the development of policies that affect insurance depository institution holding companies; and
- Participating in supervisory colleges.

The Federal Reserve relies on the state insurance regulators to participate in the activities above and to share proactively their supervisory opinions and relevant documents. These documents include the annual Own Risk Solvency Assessment (ORSA),[14] the state insurance regulator's written assessment of the ORSA, results from its examination activities, the Corporate Governance Annual Disclosure, and other state supervisory material. If the Federal Reserve determines that it is necessary to perform supervisory activities related to aspects of the supervised insurance organization that also fall under the jurisdiction of the state insurance regulator, it will communicate the rationale and result of these activities to the state insurance regulator.

By order of the Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2022–02383 Filed 2–3–22; 8:45 am]

BILLING CODE 6210–01–P

[14] Nat'l Ass'n of Ins. Comm'rs, Own Risk and Solvency Assessment (ORSA) Guidance Manual 9 (December 2017), *https://www.naic.org/store/free/ORSA_manual.pdf.*

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than February 22, 2022.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to *MA@mpls.frb.org:*

1. *Ascent BanCorp, Helena, Montana; Alan W. Bradley, Charles Shonkwiler, Christine A. N. Bradley, Kelcy Edwards, and certain minor children, all of Hamilton, Montana; Patrick Haffner, Frenchtown, Montana; Minott Pruyn, Daniel Schneiter, Haley Bradley, and a certain minor child, all of Missoula, Montana; and Daniel Wilcox, Corvallis, Montana;* a group acting in concert with Bitterroot Holding Company, Lolo, Montana, to acquire voting shares of Antler Land Company, and thereby indirectly acquire voting shares of Little Horn State Bank, both of Hardin, Montana.

Board of Governors of the Federal Reserve System, February 1, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–02345 Filed 2–3–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Cooperative Agreement To Fund Ghana Health Service

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately $800,000, for Year 1 of funding to Ghana Health Service (GHS). Funding amounts for years 2–5 will be set at continuation. The award will build laboratory and Strategic Information (SI) capacity to improve the provision of HIV testing, treatment, and retention in line with HIV epidemic control and 95–95–95 targets (95% of HIV-positive individuals knowing their status, 95% of those receiving ART [Antiretroviral therapy], and 95% of those achieving viral suppression).

DATES: The period for this award will be September 30, 2022 through September 29, 2027.

FOR FURTHER INFORMATION CONTACT: Trong Ao, Center for Global Health, Centers for Disease Control and Prevention, CDC Ghana Office, U.S. Embassy, 24 Fourth Circular Road Cantonments, Accra, Ghana, Telephone: 800–232–6348, email: *tfa8@cdc.gov.*

SUPPLEMENTARY INFORMATION: The single-source award will support the National AIDS Control Program of the GHS in the Ministry of Health to implement strategic information and laboratory strengthening activities in Ghana. GHS is a public service body established in 1996 under Act 525 as required by the 1992 Constitution of Ghana. GHS is in a unique position to conduct this work, as it is responsible for the implementation of national

health policies under the control of Ministry of Health through the GHS Governing Council. GHS has the Mandate to provide and manage comprehensive and accessible health services with special emphasis on primary health care at regional, district, and sub-district levels.

Summary of the Award

Recipient: Ghana Health Service.

Purpose of the Award: The purpose of this award is to build laboratory and SI capacity to improve the provision of HIV testing, treatment, and retention in line with HIV epidemic control and 95–95–95 targets. This award strives to build and strengthen laboratories with the appropriate diagnostic technologies, trained and skilled staff, and systems that can provide efficient services. It also strengthens SI systems, data quality assurance, and the capacity of staff responsible for managing facility-based, survey, and surveillance data operating at national and subnational levels.

Amount of Award: The approximate year 1 funding amount will be $800,000 in Federal Fiscal Year (FFY) 2022 funds, subject to the availability of funds. Funding amounts for years 2–5 will be set at continuation.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003).

Period of Performance: September 30, 2022 through September 29, 2027.

Dated: February 1, 2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–02410 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Cooperative Agreement To Fund the National AIDS Control Program, Programme National de Lutte contre le VIH/SIDA (PNLS), Democratic Republic of Congo

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately $500,000 for Year 1 of funding to the Programme National de Lutte contre le VIH/SIDA (PNLS). The award will strengthen Strategic Information (SI) activities, laboratory quality assurance services, and surveillance of new infections in Democratic Republic of Congo (DRC). This support will enhance the antiretroviral therapy (ART) cohort monitoring and delivery of HIV/AIDS services for the epidemic control in DRC. Funding amounts for years 2–5 will be set at continuation.

DATES: The period for this award will be September 30, 2022 through September 29, 2027.

FOR FURTHER INFORMATION CONTACT: Kaee Ross, Center for Global Health, Centers for Disease Control and Prevention, U.S. Embassy DRC, 498 Ave Col Lukusa, Kinshasa, Gombe, DRC, Telephone: 800–232–6348, email: *knr6@cdc.gov.*

SUPPLEMENTARY INFORMATION: The single-source award will improve data collection and analysis to produce a factual basis for evaluation and improvement of the HIV prevention, care, and treatment program in the DRC. The project will build capacity in DRC to have available, reliable data transmitted promptly for decision-making. Furthermore, the project will sustain quality assurance for rapid tests to ensure accuracy of results, and the monitoring of rapid tests used in the field.

The PNLS is a specialized program run by the Ministry of Health (MOH) in the DRC. Created on August 5, 2015 by Ministerial Decision No. 449/MSLS/CAB, the PNLS has been authorized and tasked to lead and coordinate the fight against the HIV/AIDS epidemic to achieve epidemic control. The PNLS is the governmental authority with the normative and regulatory role in the implementation of STI and HIV/AIDS control activities in the Health Zones (HZ). The PNLS has the authority to organize, review, and validate all data relative to HIV–AIDS in country. In addition, PNLS has the mission to control the quality of rapid test results provided by health care workers at facilities and to monitor how rapid tests are working in the field. Accordingly, PNLS has the sole authority and is uniquely qualified to perform the anticipated activities for this award.

Summary of the Award

Recipient: the Programme National de Lutte contre le VIH/SIDA (PNLS).

Purpose of the Award: The purpose of this award is to strengthen SI activities, laboratory quality assurance services, and surveillance of new infections in DRC. Support from this award will enhance ART cohort monitoring and delivery of HIV/AIDS services for control of the epidemic in DRC.

Amount of Award: The approximate year 1 funding amount will be $500,000 in Federal Fiscal Year (FFY) 2022 funds, subject to the availability of funds. Funding amounts for years 2–5 will be set at continuation.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003).

Period of Performance: September 30, 2022 through September 29, 2027.

Dated: February 1,2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–02411 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Cooperative Agreement To Fund the Sierra Leone Ministry of Health and Sanitation

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately $450,000 for Year 1 of funding to the Sierra Leone (SL) Ministry of Health and Sanitation. The award will build laboratory and Strategic Information (SI) capacity to improve the provision of HIV testing, treatment, and retention in line with HIV epidemic control and 95–95–95(95% of HIV-positive individuals knowing their status, 95% of those receiving ART [Antiretroviral therapy], and 95% of those achieving viral suppression) targets. Funding amounts for years 2–5 will be set at continuation.

DATES: The period for this award will be September 30, 2022 through September 29, 2027.

FOR FURTHER INFORMATION CONTACT: Trong Ao, Center for Global Health, Centers for Disease Control and Prevention, CDC Ghana Office, U.S. Embassy, 24 Fourth Circular Road Cantonments, Accra, Ghana, Telephone: 800–232–6348, Email: *tfa8@cdc.gov.*

SUPPLEMENTARY INFORMATION: The single-source award will support the National AIDS Control Program of Sierra Leone (SL) in the Ministry of Health and Sanitation to implement HIV strategic information and laboratory strengthening activities in SL. This award will build and strengthen laboratories that are equipped with the appropriate diagnostic technologies, trained and skilled staff, and systems that have the capability to provide efficient services. It will also strengthen SI systems, data quality assurance and capacity of staff responsible for managing facility-based survey and surveillance data operating at national and subnational levels. As the mandated institution to provide HIV treatment clinical services and guidelines in SL, the Sierra Leone Ministry of Health and Sanitation is in a unique position to conduct this work. The National HIV/AIDS control program is one of the specialized programs within the Ministry of Health.

Summary of the Award

Recipient: Sierra Leone Ministry of Health and Sanitation.

Purpose of the Award: The purpose of this award is to build laboratory and SI capacity to improve the provision of HIV testing, treatment, and retention in line with HIV epidemic control and 95–95–95 targets. The award will build and strengthen laboratories that are equipped with the appropriate diagnostic technologies, trained and skilled staff, and systems that have the capability to provide efficient services.

Amount of Award: The approximate year 1 funding amount will be $450,000 in Federal Fiscal Year (FFY) 2022 funds, subject to the availability of funds. Funding amounts for years 2–5 will be set at continuation.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003).

Period of Performance: September 30, 2022 through September 29, 2027.

Dated: February 1, 2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–02407 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–22–013: Rigorous Evaluation of Community-Centered Approaches for the Prevention of Community Violence.

Date: June 28–29, 2022.

Time: 8:30 a.m.–5:30 p.m., EDT.

Place: Videoconference.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Mikel Walters, Ph.D., Scientific Review Official, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, Telephone (404) 639–0913, *MWalters@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–02380 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Delegation of Authority

Notice is hereby given that the Director, Centers for Disease Control and Prevention (CDC), has delegated to the Chief Operating Officer, CDC, without the authority to redelegate, the authority vested in the Secretary of HHS by section 212(1) of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (FY 19 HHS Appropriations Act) Public Law 115–245, division B, title II, or substantially similar authorities vested in the Secretary in the future by Congress, in order to carry out international health activities.

Section 212(1) of the FY19 HHS Appropriations Act permits the Secretary of HHS to exercise authority equivalent to that available to the Secretary of State under 22 U.S.C 2669(c) to award personal services contracts for work performed in foreign countries. The authority delegated herein includes the authority to determine the necessity of negotiating, executing, and performing such contracts without regard to statutory provisions as related to the negotiation, making, and performance of contracts and performance of work in the United States.

The authority under section 212(1) is immediately revoked in the event that any subsequent fiscal year HHS appropriations act does not contain the provision currently in section 212(1) or substantially similar authority.

The Chief Operating Officer, CDC, shall consult with the Secretary of State and relevant Chief of Mission to ensure that this authority is exercised in a manner consistent with section 207 of the Foreign Service Act of 1980 and other applicable statutes administered by the Department of State.

This delegation supersedes the delegation of similar name, approved by the Director, CDC, on March 17, 2020.

This delegation became effective on January 31, 2022. The Director, CDC, affirms and ratifies any actions taken that involve the exercise of the authority delegated herein prior to the effective date of this delegation.

Sherri A. Berger,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2022–02328 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0022]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment.

DATES: The meeting will be held on February 4, 2022, from 10:00 a.m. to 5:00 p.m., EST. Times are subject to change. The meeting will be webcast live via the World Wide Web. Written comments must be received on or before February 11, 2022.

ADDRESSES: You may submit comments identified by Docket No. CDC–2022–0022 by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, Georgia 30329–4027, Attn: February 4, 2022, ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.* Do not submit comments by email. CDC does not accept comments by email.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS H24–8, Atlanta, Georgia 30329–4027; Telephone: (404) 639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: *http://www.cdc.gov/vaccines/acip/index.html.* In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on Moderna COVID–19 vaccine for individuals 18 years of age and older. A recommendation vote(s) is scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: Written comments must be received on or before February 11, 2022.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the February 4, 2022, ACIP meeting must submit a request at *https://www.cdc.gov/vaccines/acip/meetings/* no later than 9:00 a.m., EST, February 4, 2022, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by 10:00 a.m., EST, February 4, 2022. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–02445 Filed 2–2–22; 11:15 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–21GY]

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 Performance Monitoring of CDC's Comprehensive Suicide Prevention Program to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 6, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Performance Monitoring of CDC's Comprehensive Suicide Prevention Program—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) seeks OMB approval to collect information from recipients funded under the Comprehensive Suicide Prevention Program cooperative agreement (CE20–2001), hereafter known as CSP. OMB approval is requested for three years of the five-year funding period. The electronic collection of information for program and performance monitoring aligns with three of CDC's Data Modernization Initiative Key Objectives to:

- Develop and implement cloud-based approaches for automating data collection and supporting multi-directional data flows among STLT partners and CDC.
- Reduce burden for data providers and public health agencies.
- Ensure systems and services are scalable, interoperable, and adaptable to meet evolving needs.

Recipients will report progress and activity information to CDC on an annual schedule using a web-based Partners' Portal. The Partners' Portal allows recipients to fulfill their annual reporting obligations efficiently by employing user-friendly, easily accessible web-based instruments to collect necessary information for both progress reports and continuation applications including work plans. This approach enables recipients to save pertinent information from one reporting period to the next and reduces the administrative burden on the annual continuation application and the performance monitoring process. Awardee program staff can review the completeness of data needed to generate required reports, enter basic summary data for reports annually, and finalize and save required reports for upload into other reporting systems as required.

Information to be collected will provide crucial data for program performance monitoring and provide CDC with the capacity to respond in a timely manner to requests for information about the program from the Department of Health and Human Services (HHS), the White House, Congress, and other sources. Information to be collected will also strengthen CDC's ability to monitor awardee progress, provide data-driven technical assistance, and disseminate the most current surveillance data on suicide and suicide attempts.

CDC requests OMB approval for an estimated 132 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
CSP Program Recipients	Annual Progress Report	11	1	12

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–02399 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–20MR; Docket No. CDC–2022–0018]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Leptospirosis and Melioidosis Active Hospital-based Surveillance in Puerto Rico. The project aims to identify leptospirosis and melioidosis cases in Puerto Rico by establishing active surveillance for both diseases at four hospital sites for disease identification and treatment and to improve understanding of leptospirosis and melioidosis epidemiology and ecology in Puerto Rico for public health control and prevention planning.

DATES: CDC must receive written comments on or before April 5, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0018 by either of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Leptospirosis and Melioidosis Active Hospital-based Surveillance in Puerto Rico—Existing Collection in Use Without an OMB Control Number—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This project aims to identify leptospirosis and melioidosis cases in Puerto Rico by establishing active surveillance for both diseases at four hospital sites for timely disease identification and treatment and to improve understanding of leptospirosis and melioidosis epidemiology and ecology in Puerto Rico for public health control and prevention planning. Both diseases can cause outbreaks after hurricanes and flooding, especially in tropical areas, and this project is being conducted in response to an increase in leptospirosis cases after Hurricanes Irma and Maria in 2017.

Participants will be recruited from the population presenting to the emergency department of the four hospital sites with febrile illness, and will be interviewed to gather information on symptoms, possible exposures, and medical history, in addition to having diagnostic samples collected to test for leptospirosis plus or minus melioidosis (depending on presenting symptoms). Participants will also be interviewed approximately two weeks after enrollment to determine illness progression and outcome. Patients testing positive for leptospirosis, if willing, may have animal samples taken from their home or work environments to help determine the animal reservoirs related to human leptospirosis illness in Puerto Rico.

CDC requests OMB approval for an estimated 1,675 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)	Total burden (in hours)
Patient	PIFA (screening)	Up to 7,000	1	5/60	583

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Patient	PIFA (full form: sections 1–4, 11)	Up to 3,000	1	10/60	500
Patient	Consent Form	Up to 3,000	1	6/60	300
Patient	PIFF	Up to 1,000	1	10/60	167
Patient	Animal Household Survey	Up to 250	1	30/60	125
Total					1,675

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–02404 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–1014]

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 CDC Worksite Health ScoreCard (CDC ScoreCard) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on September 27, 2021 to obtain comments from the public and affected agencies. CDC received 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

CDC Worksite Health ScoreCard (CDC ScoreCard) (OMB Control No. 0920–1014, Exp. 3/31/2022)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) has established the Worksite Health ScoreCard (CDC ScoreCard), an online organizational assessment tool, to enable employers to assess the number of evidence-based health promotion interventions or strategies in their worksites to promote employee health and well-being.

The CDC ScoreCard will support small, mid-size, and large employers with three primary goals: (1) Assist employers in identifying gaps in their health promotion programs, and help them to prioritize high-impact strategies for health promotion at their worksites; (2) Improve the health and wellbeing of employees and their families through science-based workplace health interventions and promising practices; and (3) Support research and increase understanding of the organizational programs, policies, and practices that employers of various sizes and industry sectors have implemented to support healthy lifestyle behaviors.

CDC is requesting an extension to a previously approved data collection enabling existing employer users as well as new users to continue to have access to the CDC ScoreCard web-based organizational assessment tool (available at *http://www.cdc.gov/healthscorecard*).

CDC will provide outreach to, and register approximately 800 employers per year to use the online survey, which is open to employers of all sizes, industry sectors, and geographic locations across the country. CDC ScoreCard users will create a user account, complete the online assessment and receive an immediate feedback report that summarizes the current status of their worksite health program; identifies gaps in current programming; benchmarks individual employer results against other users of the system; and provides access to worksite health tools and resources to address employer gaps and priority program areas.

CDC will use the information collected to evaluate the effectiveness of the CDC ScoreCard in terms of (1) identifying success drivers for building and maintaining successful workplace health programs; (2) raising awareness and knowledge of science-based worksite health programs, policies and practices; and (3) developing additional worksite health tools and resources for employers. The information will also be used to evaluate the impact of the CDC Worksite Health Scorecard on employer adoption of worksite health programs, policies, and environmental supports.

CDC requests a three-year OMB approval for this project. Participation in the CDC ScoreCard is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 1,067.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Employers	CDC Worksite Health Scorecard Registration	800	1	5/60
	CDC Worksite Health Scorecard	800	1	75/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–02402 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–22CH Docket No. CDC–2022–0016]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled the National School COVID–19 Prevention Study. This information collection request is designed to obtain data from a nationally representative sample of K–12 public schools in the United States to describe the prevalence of COVID–19 prevention strategies (*e.g.,* mask use, physical distancing) that K–12 schools are implementing, including changes over time and differences by school-level characteristics and examine associations between school-level COVID–19 prevention strategies and COVID–19 transmission related outcomes in the school and larger community.

DATES: CDC must receive written comments on or before April 5, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0016 by either of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; phone: 404–639–7118; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

The National School COVID–19 Prevention Study—New—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC requests a one-year approval for a new information collection titled the National School COVID–19 Prevention Study (NSCPS) for the collection of information using a series of surveys to be administered to school-level designees (*e.g.,* principals) in a nationally representative sample of K–12 schools. The NSCPS has a longitudinal study design and involves five waves of data collection. This project will gather information on school-level COVID–19 prevention strategies and COVID–19 related outcomes for the last two data waves; the first three waves have been previously approved under the Public Health Emergency PRA Waiver. These data will inform CDC guidance for COVID–19 prevention in school settings.

CDC requests OMB approval for an estimated 900 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (hours)
School-level Administrator (*e.g.*, principal).	NSCPS Wave 4 and 5 Questionnaire.	600	2	45/60	900
Total					900

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–02405 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Cooperative Agreement To Fund the Ministerio de Salud de la República de Panamá (MINSA)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately $10,000,000 for Year 1 of funding to the Ministerio de Salud de la República de Panamá {MINSA}. The award will contribute to the achievement of 95–95–95 targets (95% of HIV-positive individuals knowing their status, 95% of those receiving ART [Antiretroviral therapy], and 95% of those achieving viral suppression) in Panama by introducing or scaling up high-impact HIV prevention, testing, linkage, and treatment models across the continuum of care and strengthening HIV laboratory and information systems. Funding amounts for years 2–5 will be set at continuation.

DATES: The period for this award will be September 30, 2022 through September 29, 2027.

FOR FURTHER INFORMATION CONTACT: Lily de Leon, Center for Global Health, Centers for Disease Control and Prevention, 18 Avenida 11–37, Zona 15, VHIII, Telephone: 800–232–6348, Email: *izo0@cdc.gov.*

SUPPLEMENTARY INFORMATION: The single-source award will include key HIV prevention and diagnosis activities: Index testing, differentiated service modalities at key population testing facilities, self-testing, Pre-Exposure Prophylaxis (PreP), rapid recency testing and response to clusters of recent transmission, and linkage to treatment for newly diagnosed individuals in Panama. Additionally, key HIV treatment activities will include linkage to care registries, early treatment initiation, differentiated service delivery models, opportunistic infection diagnosis and treatment, lost-to follow-up reengagement, quality assurance in Viral Load (VL) networks, and drug resistance monitoring.

MINSA is in a unique position to conduct this work, as it is the sole organization authorized to oversee the regions and medical sanitary areas covered by health institutions deemed to be scattered and decentralized in Panama. Since its creation in 1969, MINSA has served to streamline programs within these areas by setting up satellite systems in which higher ranking institutions are responsible for coordinating collaboration between medical-sanitary area officials, urban doctors, and the general hospital staff of these complex institutions.

Summary of the Award

Recipient: Ministerio de Salud de la República de Panamá (MINSA).

Purpose of the Award: The purpose of this award is to contribute to the achievement of 95–95–95 targets in Panama by introducing or scaling up high-impact HIV prevention, testing, linkage, and treatment models across the continuum of care and strengthening HIV laboratory and information systems.

Amount of Award: The approximate year 1 funding amount will be $10,000,000 in Federal Fiscal Year (FFY) 2022 funds, subject to the availability of funds. Fund amounts for years 2–5 will be set at continuation.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003).

Period of Performance: September 30, 2022 through September 29, 2027.

Dated: February 1, 2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–02406 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0020]

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 Coal Workers' Health Surveillance Program (CWHSP) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on September 14, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,*

permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Coal Workers' Health Surveillance Program (CWHSP) (OMB Control No. 0920–0020, Exp. 3/31/2022)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Institute for Occupational Safety and Health (NIOSH) is submitting an Information Collection Request (ICR) to revise the data collection instruments being utilized within the Coal Workers' Health Surveillance Program (CWHSP). This request incorporates all components of the CWHSP. Those components include: Coal Workers' X-ray Surveillance Program (CWXSP), B Reader Program, Enhanced Coal Workers' Health Surveillance Program (ECWHSP), Expanded Coal Workers' Health Surveillance Program, and National Coal Workers' Autopsy Study (NCWAS). The CWHSP is a congressionally-mandated medical examination program for monitoring the health of coal miners and was originally established under the Federal Coal Mine Health and Safety Act of 1969 with all subsequent amendments (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program, which operates in accordance with 42 CFR part 37, is useful in providing information for protecting the health of and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among U.S. coal miners. HHS proposes to revise the CWHSP regulations (42 CFR part 37) by amending existing regulatory text to allow compensation for pathologists who perform autopsies on coal miners at a market rate, on a discretionary basis as needed for public health purposes. These changes to 42 CFR 37 have necessitated this revision ICR.

The total estimated annualized burden hours of 11,741 is based on the following collection instruments:

- Coal Mine Operator Plan (2.10) and Coal Contractor Plan (2.18)—Under 42 CFR part 37, every coal operator and coal contractor in the U.S. must submit a plan approximately every 4 years, providing information on how they plan to notify their miners of the opportunity to obtain the medical examination. Completion of this form with all requested information (including a roster of current employees) takes approximately 30 minutes.
- Radiographic Facility Certification Document (2.11)—X-ray facilities seeking NIOSH approval to provide miner radiographs under the CWHSP must complete an approval packet including this form which requires approximately 30 minutes for completion.
- Miner Identification Document (2.9)—Miners who elect to participate in the CWHSP must fill out this document which requires approximately 20 minutes. This document records demographic and occupational history, as well as information required under the regulations in relation to the examinations.
- Chest Radiograph Classification Form (2.8)—NIOSH utilizes a radiographic classification system developed by the International Labour Office (ILO) in the determination of pneumoconiosis among coal miners. Physicians (B Readers) fill out this form regarding their interpretations of the radiographs (each image has at least two separate interpretations, and approximately 7% of the images require additional interpretations). Based on prior practice it takes the physician approximately 3 minutes per form.
- Physician Application for Certification (2.12)—Physicians taking the B Reader examination are asked to complete this registration form which provides demographic information as well as information regarding their medical practices. It typically takes the physician about 10 minutes to complete this form.
- Spirometry Facility Certification Document (2.14)—This form is analogous to the Radiographic Facility Certification Document (2.11) and records the spirometry facility equipment/staffing information. Spirometry facilities seeking NIOSH approval to provide miner spirometry testing under the CWHSP must complete an approval packet which includes this form. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility.
- Respiratory Assessment Form (2.13)—This form is designed to assess respiratory symptoms and certain medical conditions and risk factors. It is estimated that it will take approximately 5 minutes for this form to be administered to the miner by an employee at the facility.
- Spirometry Results Notification Form (2.15)—This form is used to: Collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; assure that the test can be done safely; record certain factors that can affect test results; provide documentation that the required components of the spirometry examination have been transmitted to NIOSH for processing; and conduct quality assurance audits and interpretation of results. It is estimated that it will take the facility approximately 20 minutes to complete this form.
- Pathologist Invoice—Under the NCWAS, the invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. Each participating pathologist may use their individual invoice as long as this statement is added. It is estimated that only 5 minutes is required for the pathologist to add this statement to the standard invoice that they routinely use.
- Pathologist Report—Under the NCWAS the pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of pneumoconiosis. The format of the autopsy reports is variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request for a clinical abstract of terminal illness and final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the pathologist's report.
- Consent, Release and History Form (2.6)—This form documents written authorization from the next-of-kin to perform an autopsy on the deceased miner. A minimum of essential information is collected regarding the deceased miner including an occupational history and a smoking history. From past experience, it is

estimated that 15 minutes is required for the next-of-kin to complete this form.

• Authorization for Payment of Autopsy Form (2.19)—Revised 42 CFR part 37.204 outlines a need for a physician pathologist to obtain written authorization from NIOSH and agreement regarding payment amount for services specified in § 37.202 (a) by completing the Authorization for Payment of Autopsy form and submitting it to the CWHSP for authorization prior to completing an autopsy on a coal miner. This is a new form. It will be completed by the pathologist who intends on conducting an autopsy and the form will collect: Demographic information on the deceased miner, characteristics of the miner's pneumoconiosis (if known by the pathologist), demographic and medical licensure information from the requesting pathologist, and proposed payment amount to complete the autopsy in accordance with § 37.203. It is estimated that 15 minutes is required for the pathologist to complete this form. The total estimated burden hours is 11,741.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
Coal Mine Operator	2.10	220	1	30/60
Coal Mine Contractor	2.18	160	1	30/60
Radiograph Facility Supervisor	2.11	20	1	30/60
Coal Miner	2.9	8,500	1	20/60
Coal Miner—Radiograph	No form required	8,500	1	15/60
B Reader Physician	2.8	10	1,760	3/60
Physicians taking the B Reader Examination	2.12	220	1	10/60
Spirometry Facility Supervisor	2.14	15	1	30/60
Spirometry Facility Employee	2.13	8,500	1	5/60
Spirometry Technician	2.15	8,500	1	20/60
Coal Miner—Spirometry	No form required	8,500	1	15/60
Pathologist	2.19	4	1	15/60
Pathologist	Invoice—No standard form	4	1	5/60
Pathologist	Pathology Report—No standard form	4	1	5/60
Next-of-kin for deceased miner	2.6	4	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–02400 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0800]

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 ''Focus Group Testing to Effectively Plan and Tailor Cancer Prevention and Control Communications Campaigns'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 26, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Focus Group Testing to Effectively Plan and Tailor Cancer Prevention and Control Communications Campaigns (OMB Control No. 0920–0800, Exp. 10/31/2021)—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the CDC's Division of Cancer Prevention and Control (DCPC) is to reduce the burden of cancer in the United States through cancer prevention, reduction of risk, early detection, and improved quality of life

for cancer survivors. Toward this end, the DCPC supports the scientific development and implementation of various health communication campaigns with an emphasis on specific cancer burdens.

This process requires testing of messages, concepts, and materials prior to their final development and dissemination, as described in the second step of the health communication process. The health communication process is a scientific model developed by the U.S. Department of Health and Human Services' National Cancer Institute to guide sound campaign development. The communication literature supports various data collection methods to conduct credible formative, concept, message, and materials testing. This process ensures that the public clearly understands cancer-specific information and concepts, are motivated to take the desired action, and do not react negatively to the messages. CDC was previously approved to collect information needed to plan and tailor cancer communication campaigns (OMB Control No. 0920–0800, Exp. 10/31/2021), and seeks OMB approval to revise the existing generic clearance to include another cancer-related communications campaign, expand the modes of data collection to include online focus groups and in-depth interviews (in-person, phone, and online), and to focus on respondents from the general public.

Information collection will involve discussions to assess numerous qualitative dimensions of cancer prevention and control messages, including but not limited to, cancer knowledge, attitudes, beliefs, behavioral intentions, information needs and sources, and compliance with cancer screening as recommended by the United States Preventive Services Task Force. Insights gained from these discussions will assist in the development and/or refinement of future campaign messages and materials. Communication campaigns and messages will vary according to the type of cancer and the qualitative dimensions of the message described above.

A separate information collection request will be submitted to OMB for approval of each discussion activity. The request will describe the purpose of the activity and include the customized information collection instruments. OMB approval is requested for three years. CDC requests OMB approval for an estimated 1,680 annual burden hours. Participation is voluntary and there are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Public	Screening Form	1,600	1	3/60
General Public	Discussion Guide	800	1	2

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–02401 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–1257; Docket No. CDC–2022–0017]

Extension of Existing Collection of Information Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies to take this opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the extension of an existing collection of information titled Assessment of Outcomes Associated with the Preventive Health and Health Services Block Grant. This assessment will assess select cross-cutting outputs and outcomes of the Preventive Health and Health Services Block Grant and demonstrate the utility of the grant on a national level.

DATES: CDC must receive written comments on or before April 5, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0017 by any of the following methods:

- *Federal eRulemaking Portal: regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffery M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffery M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Assessment of Outcomes Associated with the Preventive Health and Health Services Block Grant—Extension—Center for State, Tribal, Local and Territorial Support (CSTLTS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

For more than 35 years, the Preventive Health and Health Services Block Grant (PHHS Block Grant) has provided flexible funding for all 50 states, the District of Columbia, two American Indian tribes, five U.S. territories, and three freely associated states to address the unique public health needs of their jurisdictions in innovative and locally defined ways. First authorized by Congress in 1981 through the Public Health Service Act (Pub. L. 102–531), the fundamental and enduring purpose of the grant has been to provide grantees with flexibility and control to address their priority public health needs. In 1992, Congress amended the law to align PHHS Block Grant funding priorities with the 22 chapters specified in Healthy People (HP) 2000, a set of national objectives designed to guide health promotion and disease prevention efforts. Additional amendments included set-aside funds specifically dedicated to sex offense prevention and victim services, thus requiring grantees receiving this support to include related HP objectives and activities as part of their PHHS Block Grant—funded local programs.

CDC is establishing a comprehensive, standardized method to collect data to describe select outputs and outcomes and ensure the accountability of the PHHS Block Grant. The CDC PHHS Block Grant Measurement Framework is an innovative approach to assessing cross-cutting outputs and outcomes resulting from grantees' use of flexible grant funds. The framework defines measures that enable CDC to standardize the collection of data on grantee achievements. The CDC PHHS Block Grant Measurement Framework is an innovative approach to: Collecting data on public health infrastructure (*i.e.,* information systems, quality improvement, efficiency and effectiveness of programs, services, and operations); addressing emerging public health needs; and implementing evidence-based public health interventions.

The purpose of this information collection request (ICR) is to collect data that assess select cross-cutting outputs and outcomes of the grant (as defined by the framework measures) and that demonstrate the utility of the grant on a national level. This data collection will describe the outcomes of the PHHS Block Grant as a whole, rather than individual grantee activities or outcomes. Findings from this data collection will be used to: (1) Describe the outcomes and achievements of grantees' public health efforts and identify how the use of PHHS Block Grant funds contributed to those results, and (2) help assess how the PHHS Block Grant advances work of the public health system and provides evidence to support future budgetary requests.

The respondent universe consists of 61 PHHS Block Grant coordinators, or their designees, across 61 health departments (50 states, the District of Columbia, two tribes, five U.S. territories, and three freely associated states). The assessment will be administered to PHHS Block Grant coordinators electronically via a web-based questionnaire. A link to the assessment will be provided by email invitation. The survey will be completed once every two years. The total annualized estimated burden is 46 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
PHHS Block Grant Coordinators, or Designees.	PHHS Block Grant Assessment	61	1	45/60	46
Total	.....	.....	.....	.....	46

Jeffery M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–02403 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Cooperative Agreement To Fund the National Lung Hospital (NLH)/National Tuberculosis Program, Vietnam

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately $1,500,000, for Year 1 of funding to the National Lung Hospital (NLH)/National Tuberculosis Program (NTP). The award will support high quality TB, multi-drug resistant TB (MDR–TB), and TB/HIV programs to strengthen and expand TB and MDR–TB quality-assured diagnostic capacity

(clinical and laboratory testing); promote TB, MDR–TB, and TB/HIV prevention and integration into existing healthcare services; strengthen TB surveillance and monitoring and evaluation (M&E) and improve collaboration and coordination between TB and other programs, particularly HIV and COVID–19. Funding amounts for years 2–5 will be set at continuation.

DATES: The period for this award will be September 30, 2022 through September 29, 2027.

FOR FURTHER INFORMATION CONTACT: Amy Bailey, Center for Global Health, Centers for Disease Control and Prevention, 5th/Floor Tung Shing Building, No 2, Ngo Quyen Street, Hoan Kiem District Hanoi, Vietnam, Telephone: 800–232–6348, email: *fue8@cdc.gov.*

SUPPLEMENTARY INFORMATION: The single-source award will contribute to enhancing early and universal access to high quality prevention, diagnosis, and treatment services for TB, MDR–TB, and TB/HIV with the goal of ending TB in Vietnam by 2030.

The NLH/NTP is in a unique position to conduct this work as it is mandated by Vietnam Ministry of Health (MoH) with oversight and implementation of TB prevention and control activities in Vietnam. The NLH is the leading tertiary hospital in charge of examination and treatment of TB and lung diseases and steering TB and lung disease prevention and control activities throughout the country.

Summary of the Award

Recipient: National Lung Hospital (NLH)/National Tuberculosis Program (NTP).

Purpose of the Award: The purpose of this award is to support high quality TB, MDR–TB, and TB/HIV programs to strengthen and expand TB and MDR–TB quality-assured diagnostic capacity (clinical and laboratory testing); promote TB, MDR–TB, and TB/HIV prevention and integration into existing healthcare services; strengthen TB surveillance and M&E and improve collaboration and coordination between TB and other programs, particularly HIV and COVID–19.

Amount of Award: The approximate year 1 funding amount will be $1,500,000 in Federal Fiscal Year (FYY) 2022 funds, subject to the availability of funds. Funding amounts for years 2–5 will be set at continuation.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003).

Period of Performance: September 30, 2022 through September 29, 2027.

Dated: February 1, 2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–02412 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP); SIP22–001, Process, Outcome, and Cost Evaluation of Free Sunscreen Dispensers in Outdoor Community Settings.

Date: April 26, 2022.

Time: 11:00 a.m.–6:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Jaya Raman Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107–B, Atlanta, Georgia 30341, Telephone: (770) 488–6511, Email: *JRaman@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–02381 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): RFA–PS–22–001, Implementing Pre-exposure Prophylaxis for HIV Prevention in Syringe Service Programs; RFA–PS–22–002, Implementation Research on Telehealth Strategies to Support Retention in Care and Treatment among Antiretroviral Therapy (ART) Patients and Pre-exposure Prophylaxis (PrEP) Clients; and RFA–PS–22–004, Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era.

Date: March 30, 2022.

Time: 10:00 a.m.–5:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, 1600 Clifton Road, NE, Mailstop US8–1, Atlanta, Georgia

30329, (404) 718–8833, *GAnderson@cdc.gov*.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–02388 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Announcement of Requirements and Registration for the REACH Lark Galloway-Gilliam Nomination for Advancing Health Equity Challenge (REACH Lark Award Challenge)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the 2022 Racial and Ethnic Approaches to Community Health (REACH) Lark Galloway-Gilliam for Advancing Health Equity Award Challenge (REACH Lark Award Challenge). This biennial challenge was established in 2019 to recognize extraordinary individuals, organizations, or community coalitions associated with the REACH program whose work has contributed to the implementation of culturally tailored interventions that advance health equity, reduce health disparities, and increase community engagement to address preventable risk factors (*e.g.,* tobacco use, poor nutrition, physical inactivity, and inadequate access to clinical services).

DATES: The Challenge will accept applications from February 7, 2022 through March 18, 2022.

Award Approving Official: Rochelle P. Walensky, MD, MPH, Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry.

FOR FURTHER INFORMATION CONTACT: Kristy Mugavero, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Hwy. NE, Mailstop S107–5, Atlanta, GA 30341, Telephone: 770–488–2047, Email: *dnpaopolicy@cdc.gov.*

SUPPLEMENTARY INFORMATION: Racial and ethnic disparities in health remain pervasive across the United States. CDC administers REACH, a national program that provides funding to state and local health departments, tribes, universities, and community-based organizations. Since REACH was established in 1999, the program has demonstrated success in addressing these disparities and promoting health equity by engaging with diverse communities and implementing culturally tailored interventions. For more information about the REACH program, visit *https://www.cdc.gov/nccdphp/dnpao/state-local-programs/reach/index.htm.*

The intent of this challenge is to recognize individuals and organizations or community coalitions associated with the REACH program that meaningfully assisted with and carried out culturally tailored interventions that advance health equity, reduce health disparities, and increase community engagement to address preventable risk factors (*e.g.,* tobacco use, poor nutrition, physical inactivity, and inadequate access to clinical services) in populations or groups disproportionately affected by chronic disease; specifically, African American/Black, American Indian or Alaska Native, Asian, Hispanic or Latino, and Native Hawaiian or other Pacific Islander persons. To support the science and practice of improving health equity, this challenge can help further the goals of the REACH program by documenting and further disseminating the innovative or unique interventions employed by individuals, organizations or community coalitions applying or nominated for this award.

Subject of Challenge Competition: The challenge is authorized by Public Law 111–358, the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science Reauthorization Act of 2010 (COMPETES Act).

The ''applicant'' refers to each individual, organization, or community coalition who submits an application or nomination. The ''nominee'' refers to each individual or organization/community coalition who is nominated, whether self-nominated or nominated by a separate applicant.

Applicants will be asked to respond to a series of questions related to how the nominee assisted with and carried out culturally tailored interventions to advance health equity, reduce health disparities, and increase community engagement to address preventable risk factors (*e.g.,* tobacco use, poor nutrition, physical inactivity, and inadequate access to clinical services) in populations or groups disproportionately affected by chronic disease; specifically African American/Black, American Indian or Alaska Native, Asian, Hispanic or Latino, and Native Hawaiian or other Pacific Islander persons.

Eligibility Rules for Participating in the Challenge

The REACH Lark Award Challenge is open to the public. To be eligible for this award, nominees must meet the following eligibility requirements:

(1) Shall have completed the application (for self-nominees) or have had an application submitted on their behalf (for those nominate by others) for the competition under the rules promulgated by HHS/CDC;

(2) Shall have complied with all the requirements under this section and satisfy one of the following requirements:

a. Be a currently or previously funded CDC REACH recipient that has not previously received the REACH Lark Award in any year; or

b. Be a technical assistance provider to a former or current REACH recipient (current and past REACH recipients can be found at: *https://www.cdc.gov/nccdphp/dnpao/state-local-programs/reach/index.htm*); or

c. Be a partner organization, part of a partner network, or coalition members that collaborated on REACH-related work with a current or previously funded REACH recipient;

(3) Shall not have been a REACH Lark Award Challenge recipient in any previous year;

(4) Shall be either:

a. A U.S. citizen or legal permanent resident, eighteen years of age or older, if the nominee is an individual or group of individuals; or

b. Incorporated in and maintain a primary place of business in the United States, if the nominee is an entity; where the United States means a state, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States;

(5) Shall not be a federal entity or federal employee acting within the scope of their employment;

(6) Shall not be an employee of or contractor of CDC;

(7) Shall not use federal funds to develop COMPETES Act challenge applications for this challenge, if the applicant is a federal grantee;

(8) Shall not use federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission, if the applicant is a federal contractor;

(9) Shall not be deemed ineligible because an individual or team applicant or nominee used federal facilities or consulted with federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

(10) By participating, the applicant represents, warrants, and agrees that the entry contains accurate information. If an applicant is nominating another individual, organization, community coalition (*e.g.,* not self-nominating), the applicant must provide acknowledgement in writing that the nominee consents to being nominated.

(11) Applicants and nominees must agree to be recognized if selected as a winner and agree to participate in an interview with CDC staff to provide information that may be used by CDC staff to write a success story that describes the intervention(s) that promoted health equity. Winners and their intervention(s) may be recognized and the success story may be made public, including but not limited to, posted on the CDC's Division of Nutrition, Physical Activity, and Obesity website, the CDC website, social media, or other communication platforms, some combination of these communication channels, or all of these channels.

(12) By participating in this challenge, applicants agree to assume any and all risks related to participating in the challenge. Applicants also agree to waive claims against the federal government and its related entities, except in the case of willful misconduct, when participating in the challenge, including claims for injury; death; damage; or loss of property, money, or profits; and including those risks caused by negligence or other causes.

Registration Process for Participants

To participate and submit an application, interested parties should go to *https://www.challenge.gov.* The application requires responses to six questions; the answer to each question should be no longer than 300 words. Generally, the questions ask the applicant to describe how the nominee assisted with and carried out culturally tailored interventions that achieve health equity, reduce health disparities, and increase community engagement to address preventable risk factors (*e.g.,* tobacco use, poor nutrition, physical inactivity, and inadequate access to clinical services) in populations or groups disproportionately affected by chronic disease.

Applicants can also submit evidence that demonstrates that the criteria were met through publications, links to online content, and other forms of written material.

Amount of the Prize

No cash prize will be awarded. A maximum of two nominees (one individual and one organization or community coalition) will receive a plaque (''Winner''). While the winners may be invited to meetings by CDC, attendance at such events is not required as a condition of accepting the award.

Basis Upon Which Winners Will Be Selected

CDC's Division of Nutrition, Physical Activity, and Obesity (DNPAO) Policy Office will convene a panel of three to five internal and external experts (panel members may recuse themselves in the event of a conflict of interest related to the nominee) to review the applications and select up to two award recipients (one individual and one organization or community coalition) from all eligible entries based on:

- The extent to which the problem or challenge is clearly identified and the strategies that the nominee used to address the challenges are described.
- The extent to which nominee's work addresses one or more of the following preventable risk factors: Tobacco use, poor nutrition, physical inactivity, and inadequate access to clinical services that are related to chronic diseases such as hypertension, heart disease, type 2 diabetes, and obesity.
- The extent to which the nominee's work aligns with the National Center for Chronic Disease Prevention and Health Promotion's goals of achieving health equity by addressing social determinants of health. Examples of social determinants health include, but are not limited to the built environment, community-clinical linkages, food and nutrition security, social connectedness, and tobacco-free policies.
- The extent to which the solutions are culturally tailored, evidence or practice-based, and designed specifically to reduce health inequities for populations or groups disproportionately affected by chronic disease or related risk factors.
- The extent to which the nominee has actively and effectively engaged community members and partners across different sectors such as, but not limited to, transportation, healthcare, agriculture, emergency food systems, and faith-based organizations.
- The impact of the nominee's work in addressing preventable risk factors in populations or groups disproportionately affected by chronic disease.

Panel members will score applications on a 100-point scale to select the winners.

Additional Information

Information about the winners, such as the name and location of the individual, organization, or community coalition, priority population served, and health outcomes addressed, may be shared through press releases, the challenge website, and Division of Nutrition, Physical Activity, and Obesity and CDC Resources, and other publicly available platforms (*e.g.,* social media, CDC website, etc.). Details regarding the winners and their applications may be shared with the public as part of recognition efforts.

Applicants and nominees who are not selected for the award may be asked for permission for CDC to share information about successful interventions that promoted health equity on CDC's Division of Nutrition, Physical Activity, and Obesity website, the CDC website, social media, or other platform generally with appropriate attribution to the applicant or nominee.

The award is named in honor of Lark Galloway-Gilliam, the founding Executive Director of Community Health Councils, Inc. (CHC). CHC began in 1992 to support planning, resource development, and policy education in response to the growing health crisis in the South Los Angeles area and other under-resourced and marginalized communities throughout Los Angeles County. Lark led the CHC team to engage communities and strengthen the connections among organizations in order to improve health, eliminate disparities, and achieve health equity. Under Lark's leadership, CHC became an expert in health equity in Los Angeles, across California, and the country. Lark also served in several leadership roles, including the first president of the National REACH Coalition, the MLK Medical center Advisory Board, and the IP3 Board of Directors for Community Commons.

Compliance With Rules and Contacting Challenge Winners

Applicants, nominees, and the REACH Lark Award Challenge winners must comply with all terms and conditions of these Official Rules and winning is contingent upon fulfilling all requirements herein. The winners will be notified by email, telephone, or mail after the date of the judging.

Privacy

If applicants choose to provide HHS/CDC with personal information by registering or filling out the application form through the *Challenge.gov* website, that information will only be used to respond to contestants in matters regarding their submission, announcements of entrants, finalists, and winners of the contest. Information is not collected for commercial marketing. Winners are permitted to cite that they won this contest.

General Conditions

CDC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at CDC's sole discretion.

Participation in this Challenge constitutes an applicants' full and unconditional agreement to abide by the Challenge's Official Rules found at *https://www.Challenge.gov.*

Authority: 15 U.S.C. 3719.

Dated: February 1, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–02409 Filed 2–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10793]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by March 7, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Advantage and Prescription Drug Plan Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Field Test; *Use:* CMS is required to collect and report information on the quality of health care services and prescription drug coverage available to persons enrolled in a Medicare health or prescription drug plan under provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, the MMA under Sec. 1860D–4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding Medicare PDPs and MA plans and report this information to Medicare beneficiaries prior to the Medicare annual enrollment period. The Medicare CAHPS survey meets the requirement of collecting and publicly reporting consumer satisfaction information.

Currently, the MA & PDP CAHPS Surveys (0938–0732) are administered using a mixed mode data collection protocol (mail+phone) that includes two survey mailings and phone follow-up with non-respondents. This request is to conduct a field test with the main goal of testing the effects of new survey content and a web-based mode on patterns of response and survey scores. The test will also allow for assessment of the measurement properties of new survey items. The results of the field test will inform CMS's decision-making about updates to MA & PDP CAHPS survey content and survey administration procedures. *Form Number:* CMS–10793 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 5,000; *Total Annual Responses:* 5,000; *Total Annual Hours:* 1,290. (For policy questions regarding this collection contact Lauren K. Fuentes at 410–786–2290.)

Dated: January 31, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–02283 Filed 2–3–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Evaluation of the Child Welfare Capacity Building Collaborative (0970–0576)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Children's Bureau, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect additional data for an evaluation of the services provided to child welfare jurisdictions and Court Improvement Programs (CIPs) by the Child Welfare Capacity Building Collaborative. This new data collection is the second part of a data collection effort already underway (OMB #0970–0576, expiration 9/30/2024). This notice details the second group of instruments that will be used for data collection as part of this evaluation.

DATES: *Comments due within 60 days of publication.* In compliance with the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Capacity Building Collaborative includes three centers (Center for States, Center for Tribes, Center for Courts) funded by the Children's Bureau to provide national child welfare expertise and evidence-informed training and technical assistance services to state, tribal and U.S. territorial public child welfare agencies, and CIPs. The Centers offer services including Web-based content and resources, product development and dissemination, self-directed and group-based training, virtual learning and peer networking events, and tailored consultation, coaching, and facilitation (''tailored services''). Centers' services are being evaluated by three Center-specific evaluations and a cross-Center evaluation. *The cross-Center evaluation* examines collaboration among Centers and with federal staff, services delivered by the Centers, service recipient satisfaction with service quality, federal staff's experiences of assessment and work planning services offered by the Centers, effectiveness of Center services, how Centers apply a common ''change management approach'' in their work, what affects engagement with Center services, and the costs of Center services. *The Center for States' evaluation* consists of data collection around two research questions focusing on understanding usefulness, relevance, and satisfaction from a stakeholder perspective as well as outcomes of services. *The Center for Tribes' evaluation* examines the extent to which the Center provides effective, culturally responsive services that meet the needs of tribal child welfare programs, the satisfaction of service recipients with service quality, and service outcomes for tribal child welfare programs and stakeholders. *The Center for Courts' evaluation* assesses satisfaction with and effectiveness of service delivery; progress toward meeting Center goals and the needs of CIP to promote continuous quality improvement (CQI); and increased knowledge, collaboration, and capacity to improve court performance and child and family outcomes.

An initial set of instruments was approved and are currently in use for these evaluations. For information about these instruments, see: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202105-0970-015.* These instruments will continue to be used for data collection through July 2024.

The second group of data sources proposed include (1) a guide for conducting focus groups with teams of child welfare and CIP staff implementing tailored service projects with Center support (one version for use with states and one version for use with CIP); (2) a protocol to collect interview data from Center tailored service providers (known as Liaisons or Child Welfare Specialists) about their service provision experiences, relationships and interactions with jurisdictions and federal staff, perceptions of their role, and their Centers' approach to diversity, equity, and inclusion (DEI) services; (3) a protocol to collect interview data from jurisdiction staff implementing tailored service projects about how Centers' technical assistance addresses diversity, equity, and inclusion; (4) a protocol to collect interview/focus group data from tribal child welfare program staff about strategies and contextual factors associated with achievement of program goals, the capacity to use data for CQI and evaluation, and the outcomes of services delivered by Center for Tribes; and (5) a survey to collect feedback from CIP directors/coordinators about the CIP's experiences and satisfaction with capacity building services delivered by the Center for Courts, and the perceived impact on CIP capacity.

Respondents: Respondents to the data collection instruments will include (1) child welfare and judicial professionals that receive Center services and (2) Center tailored service providers.

Annual Burden Estimates

The following details the burden associated with the new instruments. For burden currently approved and ongoing, visit *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202105-0970-015.*

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Cross-Center: Tailored Services Team Focus Group Guide (for states)	50	1	1	50	17
Cross-Center: Tailored Services Team Focus Group Guide (for CIPs)	25	1	1	25	8
Cross-Center: Liaison/Child Welfare Specialist Interview Protocol	23	1	1	23	8
Cross-Center: Tailored Services Jurisdiction Staff DEI Interview Protocol	30	1	.75	23	8
Center for Tribes: Jurisdiction Staff Interviews	25	2	1	50	17
Center for Tribes: Jurisdiction Staff Focus Groups	25	3	1.5	113	38
Center for Courts: CIP Capacity Building Services Feedback Survey	53	2	.25	27	9

Estimated Total Annual Burden Hours: 105.

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: Sec. 5106, Pub. L. 111–320, the Child Abuse Prevention and Treatment Act Reauthorization Act of 2010, and titles IV–B and IV–E of the Social Security Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–02297 Filed 2–3–22; 8:45 am]

BILLING CODE 4184–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comprehensive Child Welfare Information System (CCWIS) Automated Function Checklist and Data Quality Plan (OMB #0970–0463)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Comprehensive Child Welfare Information System (CCWIS) information collection (OMB #0970–0463, expiration 8/31/2022). The CCWIS information collection includes the Automated Function List and the Data Quality Plan. There are no required instruments associated with the data collection and no changes to the data collection.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The CCWIS information collection includes two components:

- The Automated Function List update required pursuant to section 1355.52(i)(2); and
- The Data Quality Plan update required pursuant to section 1355.52(d)(5).

The CCWIS regulations require updates of this information to confirm that the project meets CCWIS requirements and that project costs are appropriately allocated to benefiting programs.

Respondents: Title IV–E agencies under the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Automated Function List section 1355.52(i)(2)	55	1	10	550
Data Quality Plan section 1355.52(d)(5)	55	1	40	2,200

Estimated Annual Burden Hours: 2,750.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 620 *et seq.,* 42 U.S.C. 670 *et seq.,* 42 U.S.C. 1301 and 1302.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–02363 Filed 2–3–22; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Head Start Connects: A Study of Family Support Services (OMB #0970–0538)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services seeks approval to collect information about how Head Start programs coordinate family support services. Information will be collected from Head Start staff members via surveys and focus groups.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of section 3506(c)(2)(A) 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.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The purposes of the data collection for Head Start Connects are to build knowledge about how Head Start programs (Head Start or Early Head Start grantees, delegate agencies, and

staff) coordinate family support services for parents/guardians; the characteristics of Head Start programs and staff members involved in family support services coordination; the job characteristics, work activities, and well-being of Head Start family support services staff members; and how Head Start programs can improve coordination of family support services. The data collection will build on information collected previously through case studies at six Head Start sites (OMB #0970–0538). Proposed data collection activities include three components. First, a brief web-based survey of a nationally representative sample of program directors will collect program information, including contact information for family and community partnerships managers and for family support services staff members needed for other data collection components. Second, an in-depth web-based survey of family and community partnerships managers identified by program directors will collect information about Head Start programs' structures and services for providing supports to parents and families; and the demographic characteristics, experiences, job characteristics, and well-being of managers who supervise family support services staff members. Third, three data collection activities (referred to as Parts A, B, and C) will gather information from family support services staff members. Part A, an in-depth web-based survey, will gather information about the structures and services that Head Start programs have for providing supports to parents and families; how family support services staff members reach out to and engage families in family support services; how family support services staff members work with families; and the demographic characteristics, experiences, job characteristics, and well-being of staff members who provide family support services. Part B, brief web-based surveys, will supplement Part A and will collect additional information about specific daily work activities and well-being, providing more fine-grained detail about workdays of family support services staff members. Part C, focus groups, will be conducted with a sample of family support services staff to collect information about innovations and ideas for improving how Head Start programs coordinate and individualize family support services.

Respondents: Head Start program directors, Head Start family and community partnerships managers, and Head Start family support services staff members.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per Respondent (total over request period)	Average burden per response (in hours)	Total/ annual burden (in hours)
Survey of Head Start directors	470	1	0.5	235
Survey of Head Start family and community partnerships managers	423	1	1	423
Survey of Head Start family support services staff members (Part A)	1,692	1	1	1,692
Survey of Head Start family support services staff members (Part B)	1,692	6	0.1	1,015
Focus groups of Head Start family support services staff members (Part C)	60	1	1.25	75

Estimated Total Annual Burden Hours: 3,440.

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: Section 640(a)(2)(D) and section 649 of the Improving Head Start for School Readiness Act of 2007.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–02378 Filed 2–3–22; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Current Population Survey-Child Support Supplement (OMB No.: 0970–0416)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Support Enforcement, Administration for Children and Families (ACF), is requesting that the federal Office of Management and Budget (OMB) approve a revision to an approved information collection: Current Population Survey-Child Support Supplement. The current OMB approval expires on August 31, 2022.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Current Population Survey-Child Support Supplement collects detailed information about child support agreements and awards, including both required payments and amounts received, as well as data about the socioeconomic characteristics of custodial parents and their families. Data collected pertaining to child support, and the subsequent analysis of survey data, will assist legislators and policymakers in determining the efficacy of various child support legislation.

Minor changes are being proposed for the 2023 information collection. Changes include deleting extraneous questions, updating language, and adding a few questions about customer satisfaction with the child support program. We do not anticipate that these

changes will affect the overall burden to respond to this information collection.

Respondents: Individuals and households.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Current Population Survey-Child Support Supplement	34,500	1	0.03	1,035

Estimated Total Annual Burden Hours: 1,035.

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: 13 U.S.C. 182.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–02377 Filed 2–3–22; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; U.S. Repatriation Program Forms (OMB#: 0970–0474)

AGENCY: Office of Human Services Emergency Preparedness and Response, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the U.S. Repatriation Program forms (OMB #0970–0474, expiration 4/30/2022). There are several changes requested to the eight forms. Burden estimates have also been updated.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The purpose of the U.S. Repatriation Program (Program) is to provide temporary assistance to eligible U.S. citizens and their dependents (repatriates) returned by the Department of State from a foreign country because of destitution, illness, war, threat of war, or a similar crisis, and who are without available resources, or (2) mental illness. Temporary assistance is provided upon their arrival in the United States and is available initially for up to 90 days from a repatriate's date of arrival in the United States. Temporary assistance is provided in the form of a service loan and is repayable to the U.S. Government.

Temporary assistance is defined in 42 U.S.C. 1313(c) as money payments, medical care, temporary lodging, transportation, and other goods and services necessary for the health or welfare of individuals, including guidance, counseling, and other welfare services provided to them within the United States upon their arrival in the United States. Other goods and services may include clothes, food, assistance with obtaining identification (driver's license, birth certificate), child care, and translation services.

The ACF Office of Human Services Emergency Preparedness and Response (OHSEPR), at the U.S. Department of Health and Human Services (HHS), administers the Program.

OHSEPR made changes to all eight forms to ensure the information collected aligns with Program statutes and regulations as well as the purpose and use of the form. Revisions include clarifying statutory authority and general instructions on completing and submitting the forms. These changes make the forms more user friendly. OHSEPR also reduced the burden estimates to make them more accurate.

The following is a description of the forms and the proposed revisions:

Emergency Repatriation Eligibility Application (Form RR–01)

The purpose of this form is for U.S. citizens and their dependents to request temporary assistance during an emergency repatriation. Proposed revisions include the following:

- Changing the title of the form from 'Emergency and Group Processing Form' to 'Emergency Repatriation Eligibility Application'
- Adding the following information:
  - Date and time of applicant's entry and exit to the Emergency Repatriation Center
  - Applicant's flight information
  - Name and contact information for responsible person (if main U.S. citizen applicant is a minor)
  - Gender option (X) for applicant and dependents to align with Department of State gender information on passports
  - Option for applicants and dependents to provide alternative ID number (instead of passport number)
  - Needs assessment section to determine applicant's needs
  - Details about quantity of temporary assistance requested
  - Language to signatory block to specify the meaning of signing the form
  - Materials/information provided to the repatriate
- Removing eligibility determination question regarding availability of next of kin/friends to provide resources

Emergency Repatriation Reimbursement Request (Form RR–02)

The purpose of this form is for states to request reimbursement for emergency repatriation expenditures. Proposed revisions include the following:

- Changing the title of the form from 'Emergency and Group Repatriation Financial Form' to 'Emergency Repatriation Reimbursement Request'
- Modifying information about location of service provision

- Adding planning/training/exercise as a category for reimbursement
- Clarifying instructions on documentation for allowable costs

Loan Waiver and Deferal Application (Form RR–03)

The purpose of this form is for repatriates to request a waiver or deferral of their loan for temporary assistance received through the U.S. Repatriation Program. Proposed revisions include the following:

- Changing the title of the form from 'Repatriation Loan Waiver and Deferral Request Form' to 'Loan Waiver and Deferral Application'
- Separating fixed monthly expenses from loans and liabilities
- Adding the following information:
  - Repatriate's type of current housing
  - Employer's email address
  - Option for repatriate to include additional employment
  - Assets such as checking/savings accounts
  - Language to signatory block to specify the meaning of signing this form
  - Name, relationship to repatriate, and contact information for authorized representative
- Removing Social Security Number (SSN) for dependents

Routine Repatriation Reimbursement Request (Form RR–04)

The purpose of this form is for state and local service providers to submit reimbursement requests for providing temporary assistance to repatriates under the U.S. Repatriation Program. Proposed revisions include the following:

- Changing the title of the form from 'Non-Emergency Monthly Financial Statement Form' to 'Routine Repatriation Reimbursement Request'
- Clarifying instructions on documentation for allowable costs
- Revising language on signatory block to specify the meaning of signing this form
- Removing these items:
  - State or local provider's recommendation for waiver approval
  - SSN for dependents

Repatriation Repayment and Privacy Agreement (Form RR–05)

The purpose of this form is for repatriates to agree to accept temporary assistance under the U.S. Repatriation Program, to agree to repay HHS for temporary assistance, and to allow HHS to share personal information for benefits purposes. Proposed revisions include the following:

- Changing the title of the form from 'Privacy and Repayment Agreement Form' to 'Repatriation Repayment and Privacy Agreement'
- Revising language on signatory block to specify the meaning of signing the form
- Clarifying that the Privacy Act Statement applies to Repatriation forms that collect personal identifiable information
- Adding voluntary demographic questions to align with Executive Order 13985 (*Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*)
- Adding instructions on completing the form

Refusal of Temporary Assistance (Form RR–06)

The purpose of this form is for repatriates to refuse to accept temporary assistance under the U.S. Repatriation Program after receiving information about the Program. Proposed revisions include adding the following:

- Instructions on completing the form
- The country the repatriate returned from

Temporary Assistance Extension Request (Form RR–07)

The purpose of this form is for repatriates to request an extension of temporary assistance beyond the initial 90-day eligibility period. Proposed revisions include the following:

- Removing these items:
  - SSN for dependents
  - ''other reasons'' as an option for justification of request
- Adding these items:
  - Authorized representative information
  - Sections on household income, fixed monthly expenses, and loans and liabilities
  - Language on signatory block to specify meaning of signing this form

Emergency Repatriation Request for Cost Approval and Federal Support (Form RR–08)

The purpose of this form is for states to request pre-approval for costs or federal support for an emergency repatriation. Proposed revisions include the following:

- Changing the title of the form from 'State Request for Federal Support' to 'Emergency Repatriation Request for Cost Approval and Federal Support'
- Adding separate sections for description and justification of cost pre-approvals and federal support requests
- Modifying section on Federal official's determination of state's request

Respondents: States, territories, local social service providers, administrative staff, repatriates, and authorized representatives of repatriates.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Emergency Repatriation Eligibility Application	1,000	1	.5	500
Emergency Repatriation Reimbursement Request	10	1	.3	3
Loan Waiver and Deferral Application	100	1	.5	50
Routine Repatriation Reimbursement Request	25	10	.3	75
Repatriation Repayment and Privacy Agreement	800	1	.17	136
Refusal of Temporary Assistance	300	1	.05	15
Temporary Assistance and Extension Request	25	1	.3	8
Emergency Repatriation Request for Cost Approval and Federal Support	5	10	.3	15

Estimated Total Annual Burden Hours: 802.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the

information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 1313, 24 U.S.C. 321–329.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–02374 Filed 2–3–22; 8:45 am]

BILLING CODE 4184–PL–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0082]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on February 15, 2022, from 8:30 a.m. to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: *https://youtu.be/nGRNfZ8ZHN8.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–0082. The docket will close on February 14, 2022. Submit either electronic or written comments on this public meeting by February 14, 2022. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 14, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before February 10, 2022, will be provided to the committee. Comments received after February 10, 2022, and by February 14, 2022, will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–N–0082 for ''Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Eastern Time, Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Prabhakara Atreya or Christina Vert, Center for Biologics Evaluation and

Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 240–506–4946, *CBERVRBPAC@fda.hhs.gov*; or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: Consistent with FDA's regulations, this notice is being published with less than 15 days prior to the date of the meeting based on a determination that convening a meeting of the Vaccines and Related Biological Products Advisory Committee as soon as possible is warranted. This **Federal Register** notice could not be published 15 days prior to the date of the meeting due to a recent request to amend the Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID–19 mRNA vaccine for administration to children 6 months through 4 years of age, and the need for prompt discussion of this request given the COVID–19 pandemic.

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On February 15, 2022, the committee will meet in open session to discuss a request to amend the Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID–19 mRNA vaccine for administration to children 6 months through 4 years of age.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: On February 15, 2022, from 8:30 a.m. to 5 p.m. Eastern Time the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before February 10, 2022, will be provided to the committee. Comments received after February 10, 2022, and by February 14, 2022, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 8, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 9, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Prabhakara Atreya or Christina Vert (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02390 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1411]

Drug Product Tracing: The Effect of Section 585 of the Federal Food, Drug, and Cosmetic Act—Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Drug Product Tracing: The Effect of Section 585 of the FD&C Act—Questions and Answers.'' FDA is issuing this guidance to assist industry and State and local governments in understanding the effects of the uniform national policy set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act) that was added by the Drug Supply Chain Security Act, which was enacted on November 27, 2013. This guidance is intended to help industry and States understand the law as it is currently in effect and clarify its effect on State product tracing. This guidance finalizes the draft guidance entitled ''The Effect of Uniform National Policy on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Standards: Questions and Answers'' issued on October 8, 2014.

DATES: The announcement of the guidance is published in the **Federal Register** on February 4, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note

that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–1411 for ''Drug Product Tracing: The Effect of Section 585 of the FD&C Act—Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm.7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Drug Product Tracing: The Effect of 585 of the FD&C Act—Questions and Answers.'' Title II of the Drug Quality and Security Act (Pub. L. 113–54), which is also referred to as the Drug Supply Chain Security Act (DSCSA), enacted on November 27, 2013, established a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to provide, receive, and maintain certain product and distribution information. The DSCSA also requires FDA to establish Federal standards for licensing of wholesale drug distributors and third-party logistics providers (3PLs); the Agency is publishing a proposed rule with respect to those standards concurrently with this final guidance. Section 585 of the FD&C Act (21 U.S.C. 360eee–4) sets forth a uniform national policy preempting States from establishing or continuing in effect certain standards and requirements. The guidance is intended to (1) help industry and States understand the law as it is currently in effect and (2) clarify the effect of section 585(a) on State product tracing.

This guidance finalizes the draft guidance entitled ''The Effect of Uniform National Policy on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Standards: Questions and Answers'' issued on October 8, 2014 (79 FR 60853). The draft guidance covered section 585(a) and (b) of the FD&C Act. This guidance does not cover the effect of section 585(b) of the FD&C Act, given that section 585(b) is addressed in the preamble to the proposed rule with respect to the standards for licensing wholesale distributors and 3PLs, published elsewhere in this issue of the **Federal Register**. FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include the removal of the discussion of the effect of 585(b) of the FD&C Act. The title of the guidance has been updated to reflect this change in content. In addition, editorial changes were made to improve clarity

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Drug Product Tracing: The Effect of 585 of the FD&C Act—Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://*

www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or *https://www.regulations.gov.*

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01926 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1041]

Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling—Content and Format; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling—Content and Format.'' This draft guidance provides recommendations for incorporating clinically relevant immunogenicity information into the labeling of products having immunogenicity assessments. Appropriate inclusion and consistent placement of immunogenicity information in the Prescribing Information helps to make clinically relevant information accessible to the health care practitioner and promotes the safe and effective use of prescription drug and biological products. When finalized, the recommendations in this guidance will supersede the immunogenicity labeling-specific recommendations in the guidances for industry entitled ''Labeling for Biosimilar Products'' and ''Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.''

DATES: Submit either electronic or written comments on the draft guidance by April 5, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–1041 for ''Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling—Content and Format.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Eric Brodsky, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6485, Silver Spring, MD 20993, 301–796–0855; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling—Content and Format.''

Evaluation of a therapeutic protein product's and certain select drug products' immunogenicity (*e.g.,* risk of developing anti-drug antibodies, including neutralizing antibodies) and its potential clinical impact generally plays an important role in the assessment of the product's safety and effectiveness for each proposed indication. Because some, but not all, anti-drug antibodies have been associated with safety concerns or loss of effectiveness, FDA believes that presenting immunogenicity information in a consistent manner would enable health care practitioners to more easily differentiate products associated with anti-drug antibodies having clinical effect(s) from products with anti-drug antibodies that do not have a clinically meaningful effect on pharmacokinetics, pharmacodynamics, safety, or effectiveness.

This draft guidance recommends the use of a dedicated Immunogenicity subsection (subsection 12.6) under the CLINICAL PHARMACOLOGY section. Information and statements to include in this subsection (*e.g.,* data on anti-drug antibody incidence, clinical pharmacologic effects of anti-drug antibodies) are described in the draft guidance, along with recommended content to include in other sections of the labeling (*e.g.,* summary of anti-drug antibody-associated effects on safety and/or effectiveness in the WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and/or CLINICAL STUDIES sections, as applicable). The labeling recommendations are based on: (1) Adequacy of the methodology for detection of anti-drug antibodies, (2) sufficiency of available data to draw clinical conclusions, and (3) whether the anti-drug antibodies have clinically significant effect(s). In addition to recommendations on presentation of known immunogenicity information, this draft guidance also provides recommendations for consistently stating when such information is unknown, if appropriate. The draft guidance also provides procedural information, including recommendations for updating immunogenicity information in the Prescribing Information of applicable approved products.

When finalized, this guidance will supersede the immunogenicity labeling-specific recommendations from the guidance for industry entitled ''Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' (available at *https://www.fda.gov/media/74346/download*). When finalized, this guidance will also supersede the recommendations in section IV.C.3., ADVERSE REACTIONS, Immunogenicity, of the guidance for industry entitled ''Labeling for Biosimilar Products'' (available at *https://www.fda.gov/media/96894/download*), including the statement ''Immunogenicity information for therapeutic protein products is usually placed in a subsection in the ADVERSE REACTIONS section entitled Immunogenicity'' and statements recommended for inclusion as the first paragraph in the ADVERSE REACTIONS subsection that precedes the immunogenicity data. FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling—Content and Format.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 600 have been approved under OMB control number 0910–0308. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information related to pharmacology data have been approved under OMB control number 0910–0014. The collections of information submitting biologics license applications under section 351(k) of the Public Health Service Act have been approved under OMB control number 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: January 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02348 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2398]

Population Pharmacokinetics; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Population Pharmacokinetics.'' This guidance assists sponsors in the application of population pharmacokinetics (population PK) during the drug development process to inform drug use and includes FDA's current thinking on the data and model requirements for population PK analyses submitted as part of new drug applications (NDAs), biologic license applications (BLAs), and abbreviated new drug applications (ANDAs). This guidance also provides expectations regarding the format and content of the population PK report, as well as any

labeling recommendations resulting from such analyses. This guidance finalizes the draft guidance of the same title issued on July 12, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on February 4, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–2398 for ''Population Pharmacokinetics.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Hao Zhu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3132, Silver Spring, MD 20993, 301–796–2772; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Population Pharmacokinetics.'' Population PK analyses can quantify the impact of intrinsic and extrinsic patient factors on the exposure of a drug. In conjunction with supporting exposure-response data, population PK data can be used to identify patient factors that result in a clinically significant change in drug exposure and inform the proper use of drugs. Since FDA announced the publication of the original population PK guidance in 1999, the number of applications relevant for population PK analysis has increased, and the sophistication and reliability of population PK analysis methods have improved.

This guidance finalizes the draft guidance entitled ''Population Pharmacokinetics'' issued on July 12, 2019 (84 FR 33267). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include greater detail on the use of population PK modeling for biologics, handling of time-varying covariates, additional methods and terminology typically used for population PK analyses, and updates to format and content for submitting population PK reports. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Population Pharmacokinetics.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no new collection of information. Therefore, clearance by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001. The collections of information in 21 CFR parts 600 and 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: January 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02355 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1636]

Assessment of Pressor Effects of Drugs; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Assessment of Pressor Effects of Drugs.'' This draft guidance is intended to advise sponsors on the premarketing assessment of a drug's effect on blood pressure. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure is, therefore, an important consideration in risk assessment and product labeling. This draft guidance revises the draft guidance for industry ''Assessment of Pressor Effects of Drugs'' issued on May 31, 2018.

DATES: Submit either electronic or written comments on the draft guidance by April 5, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1636 for ''Assessment of Pressor Effects of Drugs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Devi Kozeli, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4183, Silver Spring, MD 20903, 301–796–2240.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Assessment of Pressor Effects of Drugs.'' This draft guidance is intended to advise sponsors on the premarketing assessment of a drug's effect on blood pressure. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure is, therefore, an important consideration in risk assessment and product labeling.

This draft guidance revises the draft guidance entitled ''Assessment of Pressor Effects of Drugs'' issued on May 31, 2018 (83 FR 25013). Based on comments received to the docket, the draft guidance was updated to include recommendations on the design of an ambulatory blood pressure monitoring study; recommendations on the types of drugs that need an ambulatory blood pressure monitoring study; modification of Figure 1 in the draft guidance to show the relationship between the increase in 10-year atherosclerotic cardiovascular disease event risk with chronic increases in systolic blood pressure; inclusion in the guidance of Table 1, which summarizes landmark clinical trials showing the reduction of major adverse cardiac events with decreases in blood pressure with antihypertensives; and considerations for product labeling. In addition, editorial changes were made to improve clarity.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Assessment of Pressor Effects of Drugs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 addressing investigational new drug applications have been approved under OMB control number 0910–0014 and the collections of information in 21 CFR part 314 addressing new drug applications have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02371 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0335]

Authorizations of Emergency Use of Certain Drugs and Biological Products During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of three Emergency Use Authorizations (EUAs) (the Authorizations) under the Federal Food, Drug, and Cosmetic Act (FD&C Act), for use during the COVID–19 pandemic. FDA has issued one Authorization for a biological product as requested by AstraZeneca Pharmaceuticals LP (AZ), one Authorization for a drug product as requested by Pfizer, Inc. (Pfizer), and one Authorization for a drug product as requested by Merck Sharp & Dohme Corp. (Merck). The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS–CoV–2, causes the illness COVID–19. On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorization for AZ is effective as of December 8, 2021, the Authorization for Pfizer is effective as of December 22, 2021, and the Authorization for Merck is effective as of December 23, 2021.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a

determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorizations

The Authorizations follow the February 4, 2020, determination by the Secretary of HHS that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS–CoV–2, causes the illness COVID–19. Notice of the Secretary's determination was provided in the **Federal Register** on February 7, 2020 (85 FR 7316). On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the **Federal Register** on April 1, 2020 (85 FR 18250). Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has issued three authorizations for the emergency use of drugs and biological products during the COVID–19 pandemic. On December 8, 2021, FDA issued an EUA to AZ for the biological product EVUSHELD (tixagevimab co-packaged with cilgavimab), subject to the terms of the Authorization. On December 22, 2021, FDA issued an EUA to Pfizer for the drug PAXLOVID (nirmatrelvir co-packaged with ritonavir), subject to the terms of the Authorization. On December 23, 2021, FDA issued an EUA to Merck for the drug molnupiravir, subject to the terms of the Authorization. The initial Authorizations, which are included below in their entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provide an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuances of these Authorizations can be found on FDA's web page at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorizations and are available on the internet at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

U.S. FOOD & DRUG ADMINISTRATION

December 8, 2021

AstraZeneca Pharmaceuticals LP
Attention: Stacey Cromer Berman, PhD
Senior Regulatory Affairs Director and Team Lead
One MedImmune Way
Gaithersburg, MD 20878

RE: Emergency Use Authorization 104

Dear Dr. Cromer Berman:

This letter is in response to AstraZeneca Pharmaceuticals LP's (AstraZeneca) request that the Food and Drug Administration (FDA or Agency) issue an Emergency Use Authorization (EUA) for the emergency use of EVUSHELD™ (tixagevimab co-packaged with cilgavimab) for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg), as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

Tixagevimab and cilgavimab, the active components of EVUSHELD, are neutralizing IgG1 monoclonal antibodies that bind to distinct, non-overlapping epitopes within the receptor binding domain of the spike protein of SARS-CoV-2. EVUSHELD is an investigational drug and is not approved for any uses, including use as pre-exposure prophylaxis of COVID-19.

Based on the review of the data from the PROVENT clinical trial (NCT04625725), a Phase III randomized, double-blind, placebo-controlled clinical trial, it is reasonable to believe that EVUSHELD may be effective for use as pre-exposure prophylaxis of COVID-19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg), as described

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. February 4, 2020.
[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

in the Scope of Authorization (Section II), and when used under the conditions described in this authorization, the known and potential benefits of EVUSHELD outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of EVUSHELD for use as pre-exposure prophylaxis of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of EVUSHELD for pre-exposure prophylaxis of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that EVUSHELD may be effective for use as pre-exposure prophylaxis of COVID-19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg), as described in the Scope of Authorization (section II), and that, when used under the conditions described in this authorization, the known and potential benefits of EVUSHELD outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of EVUSHELD as pre-exposure prophylaxis of COVID-19 as further described in the Scope of Authorization (section II).[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Distribution of the authorized EVUSHELD will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. AstraZeneca will supply EVUSHELD to authorized distributor(s)[4], who will distribute to healthcare facilities or healthcare providers as directed by the U.S. Government, in collaboration with state and local government authorities as needed;

- EVUSHELD may only be used in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[4] "Authorized Distributor(s)" are identified by AstraZeneca as an entity or entities allowed to distribute authorized EVUSHELD.

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination[5] **or**
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Limitations on Authorized Use

- Evusheld is **not** authorized for the following uses in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- For individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.
- The use of EVUSHELD covered by this authorization must be in accordance with the authorized Fact Sheets.

Product Description

EVUSHELD is supplied as a single carton (NDC 0310-7442-02) containing 1 single-dose vial of tixagevimab injection and 1 single-dose vial of cilgavimab injection.

Tixagevimab injection (NDC 0310-8895-01) is a sterile, preservative-free, clear to opalescent and colorless to slightly yellow solution supplied in a single-dose vial for intramuscular use. The vial stoppers are not made with natural rubber latex. Each 1.5 mL contains 150 mg tixagevimab, L- histidine (2.4 mg), L- histidine hydrochloride monohydrate (3.0 mg), polysorbate 80 (0.6 mg), sucrose (123.2 mg), and Water for Injection, USP.

[5] For additional information please see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. Healthcare providers should consider the benefit-risk for an individual patient.

Cilgavimab injection (NDC 0310-1061-01) is a sterile, preservative-free, clear to opalescent and colorless to slightly yellow solution supplied in a single-dose vial for intramuscular use. The vial stoppers are not made with natural rubber latex. Each 1.5 mL contains 150 mg cilgavimab, L-histidine (2.4 mg), L- histidine hydrochloride monohydrate (3.0 mg), polysorbate 80 (0.6 mg), sucrose (123.2 mg), and Water for Injection, USP.

Unopened vials of tixagevimab and cilgavimab must be stored in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Vials must not be frozen or shaken. Unused portions must be discarded.

EVUSHELD is authorized for emergency use with the following product-specific information required to be made available to healthcare providers and to patients, parents, and caregivers, respectively, through AstraZeneca's website www.EVUSHELD.com (referred to as the "authorized labeling"):

- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) for EVUSHELD
- Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of EVUSHELD for Coronavirus Disease 2019 (COVID-19)

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of EVUSHELD, when used for pre-exposure prophylaxis of COVID-19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg) and used in accordance with this Scope of Authorization (Section II), outweigh the known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that EVUSHELD may be effective for pre-exposure prophylaxis of COVID-19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg) when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that EVUSHELD (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under an EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), EVUSHELD is authorized for use as pre-exposure prophylaxis of COVID-19 as described in this Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

AstraZeneca and Authorized Distributors[6]

A. AstraZeneca and authorized distributor(s) will ensure that EVUSHELD is distributed with the authorized labeling (i.e., Fact Sheets) will be made available to healthcare facilities and/or healthcare providers as described in Section II of this Letter of Authorization.

B. AstraZeneca and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until the product is delivered to healthcare facilities and/or healthcare providers.

C. AstraZeneca and authorized distributor(s) will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving EVUSHELD. AstraZeneca will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (i.e., Fact Sheets).

D. AstraZeneca may request changes to this authorization, including to the authorized Fact Sheets for EVUSHELD. Any request for changes to this EUA must be submitted to the Office of Infectious Diseases/Office of New Drugs/Center for Drug Evaluation and Research. Such changes require appropriate authorization prior to implementation.[7]

E. AstraZeneca may develop and disseminate instructional and educational materials (e.g., materials providing information on product administration and/or patient monitoring) that are consistent with the authorized emergency use of EVUSHELD as described in this Letter of Authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs. Any instructional and educational materials that are inconsistent with the authorized labeling for EVUSHELD are prohibited. If the Agency notifies AstraZeneca that any instructional and educational materials are

[6] "Authorized Distributor(s)" are identified by AstraZeneca as an entity or entities allowed to distribute EVUSHELD for the use authorized in this letter.

[7] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study; (8) new strengths of the authorized product, new product sources (e.g., of active pharmaceutical ingredient) or of product components. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), (7), or (8), review and concurrence is required from the Counter-Terrorism and Emergency Coordination Staff/Office of the Center Director/CDER and the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

inconsistent with the authorized labeling, AstraZeneca must cease distribution of such instructional and educational materials. Furthermore, as part of its notification, the Agency may also require AstraZeneca to issue corrective communication(s).

F. AstraZeneca will report to FDA serious adverse events and all medication errors associated with the use of EVUSHELD for its authorized use that are reported to AstraZeneca using either of the following options.

Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

Submitted reports under both options should state: "EVUSHELD use for COVID-19 under Emergency Use Authorization (EUA)." For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

G. All manufacturing, packaging, and testing sites for both drug substance and drug product will comply with current good manufacturing practice requirements of Section 501(a)(2)(B) of the Act.

H. AstraZeneca will submit information to the Agency within three working days of receipt of any information concerning significant quality problems with drug product distributed under this emergency use authorization for EVUSHELD that includes the following:

- Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or
- Information concerning any microbiological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the product to meet the established specifications.

If a significant quality problem affects unreleased product and may also impact product(s) previously released and distributed, then information should be submitted for all potentially impacted lots.

AstraZeneca will include in its notification to the Agency whether the batch, or batches, in question will be recalled.

If not included in its initial notification, AstraZeneca must submit information confirming that AstraZeneca has identified the root cause of the significant quality problems, taken corrective action, and provide a justification confirming that the corrective action is appropriate and effective. AstraZeneca must submit this

information as soon as possible but no later than 45 calendar days from the initial notification.

I. AstraZeneca will manufacture EVUSHELD to meet all quality standards and per the manufacturing process and control strategy as detailed in AstraZeneca's EUA request. AstraZeneca will not implement any changes to the description of the product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product, without notification to and concurrence by the Agency as described under condition D.

J. Through a process of inventory control, AstraZeneca and authorized distributor(s) will maintain records regarding distribution of EVUSHELD (i.e., lot numbers, quantity, receiving site, receipt date).

K. AstraZeneca will establish a process for monitoring genomic database(s) for the emergence of global viral variants of SARS-CoV-2. A summary of AstraZeneca's process should be submitted to the Agency as soon as practicable, but no later than 30 calendar days of the issuance of this letter, and within 30 calendar days of any material changes to such process. AstraZeneca will provide reports to the Agency on a monthly basis summarizing any findings as a result of its monitoring activities and, as needed, any follow-up assessments planned or conducted.

L. FDA may require AstraZeneca to assess the activity of the authorized EVUSHELD against any global SARS-CoV-2 variant(s) of interest (e.g., variants that are prevalent or becoming prevalent that harbor substitutions in the target protein or in protein(s) that interact with the target protein). AstraZeneca will perform the required assessment in a manner and timeframe agreed upon by AstraZeneca and the Agency. AstraZeneca will submit to FDA a preliminary summary report immediately upon completion of its assessment followed by a detailed study report within 30 calendar days of study completion. AstraZeneca will submit any relevant proposal(s) to revise the authorized labeling based on the results of its assessment, as may be necessary or appropriate based on the foregoing assessment.

M. AstraZeneca shall provide samples as requested of tixagevimab and of cilgavimab to the U.S. Department of Health and Human Services (HHS) for evaluation of activity against emerging global viral variants of SARS-CoV-2, including specific amino acid substitution(s) of interest (e.g., variants that are highly prevalent or that harbor substitutions in the target protein) within 5 business days of any request made by HHS. Analyses performed with the supplied quantity of the individual drug substances for tixagevimab and cilgavimab may include, but are not limited to, cell culture potency assays, protein binding assays, cell culture variant assays (pseudotyped virus-like particles and/or authentic virus), and *in vivo* efficacy assays.

N. AstraZeneca must provide the following information to the Agency:

- All anti-drug antibody (ADA) assessments that have not been completed at the time of this authorization for subjects from the PROVENT clinical trial

for days 1, 29, 58, and 183 by April 22, 2022.

- Interim analysis results through Day 28 for the first 50 subjects to receive a second dose from the PROVENT repeat-dose sub-study by April 22, 2022.
- AstraZeneca must conduct an additional study attempting to select for SARS-CoV-2 with reduced susceptibility to tixagevimab in culture. Such study must employ alternative strategies as agreed upon between AstraZeneca and the Agency. AstraZeneca must provide the Agency with a proposed protocol by January 7, 2022. AstraZeneca must submit a report of summary findings as soon as available, but no later than June 30, 2022.
- Report from AstraZeneca's study evaluating the potential for tixagevimab and cilgavimab to mediate antibody-dependent enhancement of infection using sub-saturating concentrations of each monoclonal antibody by June 30, 2022.
- Final results from PROVENT and STORM CHASER by December 30, 2022. Results, to include baseline and all subsequent study visits, of the following biomarkers from the PROVENT repeat-dose sub-study: d-dimer, P-selectin, thrombin, and Factor VIII.
- Topline data, to include safety, pharmacokinetic, ADA, and biomarker results for thrombotic events from the first 9 months of the PROVENT repeat-dose sub-study by January 31, 2023.
- Monthly aggregate reports for serious adverse events in the Cardiac Disorder System Order Class (SOC) and other non-cardiac thrombotic serious adverse events.

O. AstraZeneca and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Facilities to Whom EVUSHELD Is Distributed and Healthcare Providers Administering EVUSHELD

P. Healthcare facilities and healthcare providers will ensure that they are aware of the Letter of Authorization, and the terms herein, and that the authorized Fact Sheets are made available to healthcare providers and to patients, parents, and caregivers, respectively, through appropriate means, prior to administration of EVUSHELD.

Q. Healthcare facilities and healthcare providers receiving EVUSHELD will track all serious medication errors and adverse events that are considered to be potentially attributable to EVUSHELD use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports should state, "EVUSHELD use for COVID-19 under Emergency Use Authorization" at the beginning of the question "Describe Event" for further analysis. A copy of the completed FDA Form 3500 should also be provided to AstraZeneca per the instructions in the authorized labeling.

R. Healthcare facilities and healthcare providers will ensure that appropriate storage and cold chain is maintained until the product is administered consistent with the terms of this letter and the authorized labeling.

S. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensing and administration of EVUSHELD for the use authorized in this letter (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

T. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by AstraZeneca and/or FDA. Such records will be made available to AstraZeneca, HHS, and FDA for inspection upon request.

U. Healthcare facilities and providers will report therapeutics information and utilization data as directed by the U.S. Department of Health and Human Services.

Conditions Related to Printed Matter, Advertising, and Promotion

V. All descriptive printed matter, advertising, and promotional materials relating to the use of EVUSHELD under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the Act, as applicable, and FDA implementing regulations. References to "approved labeling", "permitted labeling" or similar terms in these requirements shall be understood to refer to the authorized labeling for the use of EVUSHELD under this authorization. In addition, such materials shall:

- Be tailored to the intended audience.
- Not take the form of reminder advertisements, as that term is described in 21 CFR 202.1(e)(2)(i), 21 CFR 200.200 and 21 CFR 201.100(f).
- Present the same risk information relating to the major side effects and contraindications concurrently in the audio and visual parts of the presentation for advertising and promotional materials in audio-visual format.
- Be accompanied by the authorized labeling, if the promotional materials are not subject to Section 502(n) of the Act.
- Be submitted to FDA accompanied by Form FDA-2253 at the time of initial dissemination or first use.

If the Agency notifies AstraZeneca that any descriptive printed matter, advertising or promotional materials do not meet the terms set forth in conditions V-X of this EUA, AstraZeneca must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency's notification. Furthermore, as part of its notification, the Agency may also require AstraZeneca to issue corrective communication(s).

W. No descriptive printed matter, advertising, or promotional materials relating to the use of EVUSHELD under this authorization may represent or suggest that EVUSHELD is safe or effective when used as pre-exposure prophylaxis of COVID-19 as described in the Scope of Authorization (Section II).

X. All descriptive printed matter, advertising, and promotional material, relating to the use of EVUSHELD under this authorization clearly and conspicuously shall state that:

- EVUSHELD has not been approved, but has been authorized for emergency use by FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg); and
- The emergency use of EVUSHELD is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,
/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

December 22, 2021

Pfizer, Inc.
Attention: Karen Baker
Director, Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

RE: Emergency Use Authorization 105

Dear Ms. Baker:

This letter is in response to Pfizer, Inc.'s (Pfizer) request that the Food and Drug Administration (FDA or Agency) issue an Emergency Use Authorization (EUA) for the emergency use of PAXLOVID (nirmatrelvir co-packaged with ritonavir) for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults and pediatric patients pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

PAXLOVID is comprised of nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, co-packaged with ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor. Ritonavir, which has no activity against SARS-CoV-2 on its own, is included to inhibit the CYP3A-mediated metabolism of nirmatrelvir and consequently increase nirmatrelvir plasma concentrations to levels anticipated to inhibit SARS-CoV-2 replication. PAXLOVID is not approved for any use, including for use for the treatment of COVID-19.

Based on the totality of scientific evidence available to FDA, including data from the clinical trial EPIC-HR (NCT04960202), a Phase 2/3 randomized, double blind, placebo-controlled clinical trial, it is reasonable to believe that PAXLOVID may be effective for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, February 4, 2020.
[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization (Section II), and when used under the conditions described in this authorization, the known and potential benefits of PAXLOVID outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of PAXLOVID for the treatment of mild-to-moderate COVID-19 in certain adults and pediatric patients, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of PAXLOVID for the treatment of COVID-19, when administered as described in the Scope of Authorization (Section II), meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that PAXLOVID may be effective for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization (section II), and that, when used under the conditions described in this authorization, the known and potential benefits of PAXLOVID outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Distribution of the authorized PAXLOVID will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. Pfizer will supply PAXLOVID to authorized distributor(s)[4], who will distribute to

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[4] "Authorized Distributor(s)" are identified by Pfizer as an entity or entities allowed to distribute authorized PAXLOVID.

healthcare facilities or healthcare providers as directed by the U.S. Government, in collaboration with state and local government authorities as needed;

- PAXLOVID may only be used by healthcare providers to treat mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk[5] for progression to severe COVID-19, including hospitalization or death;

  Limitations on Authorized Use

  - PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.[6]
  - PAXLOVID is not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19.
  - PAXLOVID is not authorized for use for longer than 5 consecutive days.

- PAXLOVID may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which PAXLOVID belongs (i.e., anti-infectives).[7]

- The use of PAXLOVID covered by this authorization must be in accordance with the authorized Fact Sheets.

Product Description

PAXLOVID consists of two 150 mg tablets of nirmatrelvir that are co-packaged with one 100 mg tablet ritonavir.

Nirmatrelvir is supplied as an oval, pink, immediate-release, film-coated tablet debossed with "PFE" on one side and "3CL" on the other side.

Ritonavir is supplied as a white, film-coated, ovaloid tablet debossed with the "a" logo and the code NK.

The authorized storage and handling information for PAXLOVID is included in the authorized Fact Sheet for Healthcare Providers.

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[5] For information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the Centers for Disease Control and Prevention (CDC) website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.

[6] Patients requiring hospitalization due to severe or critical COVID-19 after starting treatment with PAXLOVID may complete the full 5-day treatment course per the healthcare provider's discretion.

[7] The term "State" includes any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. See section 201(a)(1) of the Act.

PAXLOVID is authorized for emergency use with the following product-specific information required to be made available to healthcare providers and to patients, parents, and caregivers, respectively, through Pfizer's website www.COVID19oralRX.com (referred to as the "authorized labeling"):

- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) for PAXLOVID
- Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of PAXLOVID for Coronavirus Disease 2019 (COVID-19)

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of PAXLOVID, when used for the treatment of COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh the known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that PAXLOVID may be effective for the treatment of COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that PAXLOVID (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of PAXLOVID under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), PAXLOVID is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer and Authorized Distributors[8]

A. Pfizer and authorized distributor(s) will ensure that PAXLOVID is distributed and the authorized labeling (i.e., Fact Sheets) will be made available to healthcare facilities and/or healthcare providers as described in Section II of this Letter of Authorization.

[8] Supra at Note 4.

B. Pfizer and authorized distributor(s) will ensure that appropriate storage is maintained until the product is delivered to healthcare facilities and/or healthcare providers.

C. Pfizer and authorized distributor(s) will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving PAXLOVID. Pfizer will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (i.e., Fact Sheets).

D. Pfizer may request changes to this authorization, including to the authorized Fact Sheets for PAXLOVID. Any request for changes to this EUA must be submitted to the Office of Infectious Diseases/Office of New Drugs/Center for Drug Evaluation and Research. Such changes require appropriate authorization prior to implementation.[9]

E. Pfizer may develop and disseminate instructional and educational materials (e.g., materials providing information on product administration and/or patient monitoring) that are consistent with the authorized emergency use of PAXLOVID as described in this Letter of Authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs. Any instructional and educational materials that are inconsistent with the authorized labeling for PAXLOVID are prohibited. If the Agency notifies Pfizer that any instructional and educational materials are inconsistent with the authorized labeling, Pfizer must cease distribution of such instructional and educational materials. Furthermore, as part of its notification, the Agency may also require Pfizer to issue corrective communication(s).

F. Pfizer will report to FDA serious adverse events and all medication errors associated with the use of PAXLOVID for its authorized use that are reported to Pfizer using either of the following options.

Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

[9] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study; (8) new strengths of the authorized product, new product sources (e.g., of active pharmaceutical ingredient) or of product components. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), (7), or (8), review and concurrence is required from the Counter-Terrorism and Emergency Coordination Staff/Office of the Center Director/CDER and the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

Submitted reports under both options must state: "PAXLOVID use for COVID-19 under Emergency Use Authorization (EUA)." For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

G. All manufacturing, packaging, and testing sites for both drug substance and drug product will comply with current good manufacturing practice requirements of Section 501(a)(2)(B) of the Act.

H. Pfizer will submit information to the Agency within three working days of receipt of any information concerning significant quality problems with drug product distributed under this emergency use authorization for PAXLOVID that includes the following:

- Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or
- Information concerning any microbiological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the product to meet the established specifications.

If a significant quality problem affects unreleased product and may also impact product(s) previously released and distributed, then information must be submitted for all potentially impacted lots.

Pfizer will include in its notification to the Agency whether the batch, or batches, in question will be recalled.

If not included in its initial notification, Pfizer must submit information confirming that Pfizer has identified the root cause of the significant quality problems, taken corrective action, and provide a justification confirming that the corrective action is appropriate and effective. Pfizer must submit this information as soon as possible but no later than 45 calendar days from the initial notification.

I. Pfizer will manufacture PAXLOVID to meet all quality standards and per the manufacturing process and control strategy as detailed in Pfizer's EUA request. Pfizer will not implement any changes to the description of the product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product, without notification to and concurrence by the Agency as described under condition D.

J. Through a process of inventory control, Pfizer and authorized distributor(s) will maintain records regarding distribution of PAXLOVID (i.e., lot numbers, quantity, receiving site, receipt date).

K. Pfizer will establish a process for monitoring genomic database(s) for the emergence of global viral variants of SARS-CoV-2 and will provide reports to the Agency on a monthly basis summarizing any findings as a result of its monitoring activities and, as needed, any follow-up assessments planned or conducted. Updated data listings summarizing amino acid variability should be provided at least monthly for Mpro amino acid sequences, and at least every 2 months for Mpro cleavage site amino acid sequences. The data listings should include a cumulative list of amino acid polymorphisms detected in genomic database(s), highlighting changes/variants that are increasing in frequency from the previous month.

L. FDA may require Pfizer to assess the activity of the authorized PAXLOVID against any global SARS-CoV-2 variant(s) of interest (e.g., variants that are prevalent or becoming prevalent that harbor substitutions in the target protein or in protein(s) that interact with the target protein). Pfizer will perform the required assessment in a manner and timeframe agreed upon by Pfizer and the Agency. Pfizer will submit to FDA a preliminary summary report immediately upon completion of its assessment followed by a detailed study report within 30 calendar days of study completion. Pfizer will submit any relevant proposal(s) to revise the authorized labeling based on the results of its assessment, as may be necessary or appropriate based on the foregoing assessment.

M. Pfizer shall provide samples as requested of the authorized nirmatrelvir to the U.S. Department of Health and Human Services (HHS) for evaluation of activity against emerging global viral variants of SARS-CoV-2, including specific amino acid substitution(s) of interest (e.g., variants that are highly prevalent or that harbor substitutions in the target protein(s) or target cleavage sites) within 5 business days of any request made by HHS. Analyses performed with the supplied quantity of authorized nirmatrelvir may include, but are not limited to, cell culture potency assays, biochemical assays, and in vivo efficacy assays.

N. Pfizer must provide the following information to the Agency:

1. Pfizer must conduct cell culture phenotypic analyses of recombinant SARS-CoV-2 viruses or replicons carrying specific amino acid changes potentially associated with reduced nirmatrelvir susceptibility in nonclinical or clinical studies, or polymorphisms emerging in novel SARS-CoV-2 variants. Specific amino acid changes that should be characterized include the following:
    - amino acid changes associated with reduced nirmatrelvir susceptibility in biochemical assays,
    - natural amino acid polymorphisms in Mpro that come in contact with or in close proximity (<5 Å) to bound nirmatrelvir,
    - amino acid changes associated with nirmatrelvir/ritonavir treatment emergence, treatment failure, or prolonged virologic shedding or rebound in clinical trials, and
    - amino acid polymorphisms identified in resistance surveillance analyses.

   Amino acid changes in both Mpro and Mpro cleavage sites should be considered in these analyses. Specific amino acid changes of interest for

phenotypic characterization in cell culture assays currently include Mpro substitutions Y54A, E55L, F140A, S144A, E166A, H172Y, Q189K, and A260V. When warranted due to technical challenges, alternative approaches to the requested cell culture assays will be considered on a case-by-case basis. Pfizer must submit a preliminary summary report no later than February 28, 2022 for any currently ongoing studies, and at least every 6 months thereafter as additional data accumulate.

2. Pfizer must evaluate the cell culture antiviral activity of nirmatrelvir against an authentic SARS-CoV-2 isolate representative of the Omicron variant. Pfizer must submit a summary report no later than February 28, 2022.
3. Pfizer must conduct studies characterizing potential nirmatrelvir resistance mechanisms in SARS-CoV-2 in cell culture, including selection and genotypic and phenotypic characterization of nirmatrelvir-resistant virus. Pfizer must submit a brief monthly progress report on these studies, a preliminary summary report no later than April 30, 2022, and a final report within 30 days of study completion.
4. Pfizer must complete analyses of SARS-CoV-2 shedding and nucleotide sequencing from the EPIC-HR clinical trial. Viral sequencing analyses should be conducted for all clinical samples with sufficient viral RNA levels, including samples collected at baseline, on-treatment and post-treatment, to identify and characterize the potential emergence or persistence of amino acid changes associated with PAXLOVID treatment. Pfizer must submit a summary of available data (including analysis-ready datasets) no later than February 28, 2022, and a final report and associated datasets (including analysis-ready datasets and raw fastq NGS data) no later than April 30, 2022.
5. Pfizer will submit the clinical study report containing data from all enrolled subjects in the EPIC-HR clinical trial no later than January 15, 2022.
6. Pfizer will provide results from a safety and pharmacokinetic study evaluating PAXLOVID as treatment of mild-to-moderate COVID-19 in patients with severe renal impairment (for both patients requiring and not requiring hemodialysis), with the study protocol submitted no later than March 31, 2022.
7. Pfizer will provide the audited final report of the rat PPND study, *An Oral (Gavage) Study of the Effects of PF-07321332 on Pre- and Postnatal Development, Including Maternal Function in Rats,* no later than April 30, 2022.

O. Pfizer and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Facilities to Whom PAXLOVID Is Distributed and Healthcare Providers Administering PAXLOVID

P. Healthcare facilities and healthcare providers will ensure that they are aware of the Letter of Authorization, and the terms herein, and that the authorized Fact Sheets are made

available to healthcare providers and to patients, parents, and caregivers, respectively, through appropriate means, prior to administration of PAXLOVID.

Q. Healthcare facilities and healthcare providers receiving PAXLOVID will track all serious medication errors and adverse events that are considered to be potentially attributable to PAXLOVID use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports must state, "PAXLOVID use for COVID-19 under Emergency Use Authorization" at the beginning of the question "Describe Event" for further analysis. A copy of the completed FDA Form 3500 must also be provided to Pfizer per the instructions in the authorized labeling.

R. Healthcare facilities and healthcare providers will ensure that appropriate storage is maintained until the product is administered consistent with the terms of this letter and the authorized labeling.

S. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensing and administration of PAXLOVID for the use authorized in this letter (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

T. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by Pfizer and/or FDA. Such records will be made available to Pfizer, HHS, and FDA for inspection upon request.

U. Healthcare facilities and providers will report therapeutics information and utilization data as directed by HHS.

Conditions Related to Printed Matter, Advertising, and Promotion

V. All descriptive printed matter, advertising, and promotional materials relating to the use of PAXLOVID under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the Act, as applicable, and FDA implementing regulations. References to "approved labeling", "permitted labeling" or similar terms in these requirements shall be understood to refer to the authorized labeling for the use of PAXLOVID under this authorization. In addition, such materials shall:

- Be tailored to the intended audience.
- Not take the form of reminder advertisements, as that term is described in 21 CFR 202.1(e)(2)(i), 21 CFR 200.200 and 21 CFR 201.100(f).

- Present the same risk information relating to the major side effects and contraindications concurrently in the audio and visual parts of the presentation for advertising and promotional materials in audio-visual format.
- Be accompanied by the authorized labeling, if the promotional materials are not subject to Section 502(n) of the Act.
- Be submitted to FDA accompanied by Form FDA-2253 at the time of initial dissemination or first use.

If the Agency notifies Pfizer that any descriptive printed matter, advertising or promotional materials do not meet the terms set forth in conditions V-X of this EUA, Pfizer must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency's notification. Furthermore, as part of its notification, the Agency may also require Pfizer to issue corrective communication(s).

W. No descriptive printed matter, advertising, or promotional materials relating to the use of PAXLOVID under this authorization may represent or suggest that PAXLOVID is safe or effective when used for the treatment of COVID-19.

X. All descriptive printed matter, advertising, and promotional material, relating to the use of PAXLOVID under this authorization clearly and conspicuously shall state that:

- PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high-risk for progression to severe COVID-19, including hospitalization or death; and

- The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

December 23, 2021

Merck Sharp & Dohme Corp.
Attention: Sushma Kumar, PhD, PMP
Senior Director, Global Regulatory Affairs and Clinical Safety
1 Merck Drive
PO Box 100
Whitehouse Station, NJ 08889-0100

RE: Emergency Use Authorization 108

Dear Dr. Kumar:

This letter is in response to Merck Sharp & Dohme Corp.'s (Merck) request that the Food and Drug Administration (FDA or Agency) issue an Emergency Use Authorization (EUA) for the emergency use of molnupiravir for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

Molnupiravir is a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis. Molnupiravir is not FDA-approved for any uses, including use as treatment for COVID-19.

Based on the review of the data from the MOVe-OUT clinical trial (NCT04575597), a Phase III randomized, double-blind, placebo-controlled clinical trial studying molnupiravir for the treatment of non-hospitalized patients with mild-to-moderate COVID-19 who are at high risk for progression to severe COVID-19, including hospitalization or death, it is reasonable to believe that molnupiravir may be effective for the treatment of mild-to-moderate COVID-19 in adults

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, February 4, 2020.
[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate, as described in the Scope of Authorization (Section II), and when used under the conditions described in this authorization, the known and potential benefits of molnupiravir outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of molnupiravir for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of molnupiravir for treatment of mild-to-moderate COVID-19, when administered as described in the Scope of Authorization (Section II), meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that molnupiravir may be effective for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization (section II), and that, when used under the conditions described in this authorization, the known and potential benefits of molnupiravir outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of molnupiravir for the treatment of mild-to-moderate COVID-19 in adults as further described in the Scope of Authorization (section II).[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Distribution of the authorized molnupiravir will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. Merck will supply molnupiravir to authorized distributor(s)[4], who will distribute to healthcare facilities or healthcare providers as directed by the U.S. Government, in collaboration with state and local government authorities as needed;

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[4] "Authorized Distributor(s)" are identified by Merck as an entity or entities allowed to distribute authorized molnupiravir.

- Molnupiravir may only be used for the treatment of mild-to-moderate COVID-19 in adults:
    - With positive results of direct SARS-CoV-2 viral testing, and
    - Who are at high-risk[5] for progression to severe COVID, including hospitalization or death, and
    - For whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.

    Limitations on Authorized Use

    - Molnupiravir is not authorized for use in patients who are less than 18 years of age.
    - Molnupiravir is not authorized for initiation of treatment in patients requiring hospitalization due to COVID-19.[6] Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19.
    - Molnupiravir is not authorized for use for longer than 5 consecutive days.
    - Molnupiravir is not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19.
- Molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state[7] law to prescribe drugs in the therapeutic class to which molnupiravir belongs (i.e., anti-infectives).
- The use of molnupiravir covered by this authorization must be in accordance with the authorized Fact Sheets.

Product Description

The authorized molnupiravir is supplied as a bottle (NDC-0006-5055-06, NDC-0006-5055-07) containing a sufficient quantity of molnupiravir 200 mg capsules to complete a full treatment course (i.e., 40 capsules). Molnupiravir is manufactured as a Swedish Orange, opaque capsule containing the Merck corporate logo and "82" printed in white ink.

[5] For information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the Centers for Disease Control and Prevention (CDC) website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.

[6] Patients requiring hospitalization after starting treatment with molnupiravir may complete the full 5 day treatment course per the healthcare provider's discretion.

[7] The term "State" includes any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. See section 201(a)(1) of the Act.

The authorized storage and handling information is included in the authorized Fact Sheet for Healthcare Providers.

Molnupiravir is authorized for emergency use with the following product-specific information required to be made available to healthcare providers and to patients and caregivers, respectively, through Merck's website www.molnupiravir.com (referred to as the "authorized labeling"):

- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) for molnupiravir
- Fact Sheet for Patients and Caregivers: Emergency Use Authorization (EUA) of molnupiravir for Coronavirus Disease 2019 (COVID-19)

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of molnupiravir, when used for the treatment of COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh the known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that molnupiravir may be effective for the treatment of COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that molnupiravir (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of molnupiravir product under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), molnupiravir is authorized for the treatment of COVID-19 as described in this Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Merck and Authorized Distributors[8]

A. Merck and authorized distributor(s) will ensure that molnupiravir is distributed and the authorized labeling (i.e., Fact Sheets) will be made available to healthcare facilities and/or healthcare providers as described in Section II of this Letter of Authorization.

[8] Supra at Note 4.

B. Merck and authorized distributor(s) will ensure that appropriate storage is maintained until the product is delivered to healthcare facilities and/or healthcare providers.

C. Merck and authorized distributor(s) will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving molnupiravir. Merck will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (i.e., Fact Sheets).

D. Merck may request changes to this authorization, including to the authorized Fact Sheets for molnupiravir. Any request for changes to this EUA must be submitted to the Office of Infectious Diseases/Office of New Drugs/Center for Drug Evaluation and Research. Such changes require appropriate authorization prior to implementation.[9]

E. Merck may develop and disseminate instructional and educational materials (e.g., materials providing information on product administration and/or patient monitoring) that are consistent with the authorized emergency use of molnupiravir as described in this Letter of Authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs. Any instructional and educational materials that are inconsistent with the authorized labeling for molnupiravir are prohibited. If the Agency notifies Merck that any instructional and educational materials are inconsistent with the authorized labeling, Merck must cease distribution of such instructional and educational materials. Furthermore, as part of its notification, the Agency may also require Merck to issue corrective communication(s).

F. Merck will report to FDA serious adverse events and all medication errors associated with the use of molnupiravir for its authorized use that are reported to Merck using either of the following options.

Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

[9] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study; (8) new strengths of the authorized product, new product sources (e.g., of active pharmaceutical ingredient) or of product components. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), (7), or (8), review and concurrence is required from the Counter-Terrorism and Emergency Coordination Staff/Office of the Center Director/CDER and the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

Submitted reports under both options must state: "Molnupiravir use for COVID-19 under Emergency Use Authorization (EUA)." For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

G. All manufacturing, packaging, and testing sites for both drug substance and drug product will comply with current good manufacturing practice requirements of Section 501(a)(2)(B) of the Act.

H. Merck will submit information to the Agency within three working days of receipt of any information concerning significant quality problems with drug product distributed under this EUA for molnupiravir that includes the following:

- Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or
- Information concerning any microbiological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the product to meet the established specifications.

If a significant quality problem affects unreleased product and may also impact product(s) previously released and distributed, then information must be submitted for all potentially impacted lots.

Merck will include in its notification to the Agency whether the batch, or batches, in question will be recalled.

If not included in its initial notification, Merck must submit information confirming that Merck has identified the root cause of the significant quality problems, taken corrective action, and provide a justification confirming that the corrective action is appropriate and effective. Merck must submit this information as soon as possible but no later than 45 calendar days from the initial notification.

I. Merck will manufacture molnupiravir to meet all quality standards and per the manufacturing process and control strategy as detailed in Merck's EUA request. Merck will also test the active pharmaceutical ingredient (API) starting material for additional quality attributes agreed upon by Merck and the Agency. Merck will not implement any changes to the description of the product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product, without notification to and concurrence by the Agency as described under condition D.

J. Through a process of inventory control, Merck and authorized distributor(s) will maintain records regarding distribution of molnupiravir (i.e., lot numbers, quantity, receiving site, receipt date).

K. Merck will establish a process for monitoring genomic database(s) for the emergence of global viral variants of SARS-CoV-2. A summary of Merck's process should be submitted to the Agency as soon as practicable, but no later than 30 calendar days of the issuance of this letter, and within 30 calendar days of any material changes to such process. Merck will provide reports to the Agency on a monthly basis summarizing any findings as a result of its monitoring activities and, as needed, any follow-up assessments planned or conducted.

L. FDA may require Merck to assess the activity of the authorized molnupiravir against any global SARS-CoV-2 variant(s) of interest (e.g., variants that are prevalent or becoming prevalent that harbor substitutions in the target protein or in protein(s) that interact with the target protein). Merck will perform the required assessment in a manner and timeframe agreed upon by Merck and the Agency. Merck will submit to FDA a preliminary summary report immediately upon completion of its assessment followed by a detailed study report within 30 calendar days of study completion. Merck will submit any relevant proposal(s) to revise the authorized labeling based on the results of its assessment, as may be necessary or appropriate based on the foregoing assessment.

M. Merck shall provide samples as requested of molnupiravir to the U.S. Department of Health and Human Services (HHS) for evaluation of activity against emerging global viral variants of SARS-CoV-2, including specific amino acid substitution(s) of interest (e.g., variants that are highly prevalent or that harbor substitutions in the target protein) within 5 business days of any request made by HHS. Analyses performed with the supplied quantity of molnupiravir may include, but are not limited to, cell culture potency assays, biochemical assays, and in vivo efficacy assays.

N. Merck must provide the following information to the Agency:

1. Merck will conduct a thorough investigation into the differences in efficacy observed in the first and second half of Part 2 of trial MK-4482-002. This assessment should involve the synthesis of data, including, but not limited to, additional baseline serology testing, a detailed comparison of baseline characteristics (including demographic, clinical disease, and virologic characteristics), and an exploration of potential differences in standard of care by region and over time. Merck will submit a report of its findings to the Agency. Merck will submit a preliminary report no later than March 31, 2022 and a final report incorporating available serology results no later than September 30, 2022.
2. Merck will submit the complete viral shedding results and full genome SARS-CoV-2 nucleotide sequencing results from the full randomized population in study MK-4482-002 Part 2. Viral sequencing analyses should include all Baseline and End-of-Treatment (Day 5) samples with sufficient RNA levels for analysis, as well as all Post-Treatment samples with viral

RNA levels ≥100,000 copies/mL. Cell culture infectivity assessments should be conducted for any clinical specimens in which amino acid changes were detected in the SARS-CoV-2 spike protein. Submissions should include summary report(s) and associated datasets (including analysis-ready datasets and raw fastq NGS data). A separate summary should be provided describing the results of the viral shedding and sequencing analyses specifically from immunocompromised patients. Merck will submit a preliminary report and associated datasets for the viral shedding and Baseline/Day 5 sequencing analyses no later than March 31, 2022, and a final report and datasets including the remaining analyses no later than June 30, 2022.

3. Merck will evaluate the cell culture antiviral activity of molnupiravir against an authentic SARS-CoV-2 isolate representative of the Omicron variant. Merck must submit a study report no later than February 28, 2022.
4. Merck will conduct a pharmacokinetic (PK) study in wild type Fisher 344 rats to establish if NHC or NHC-TP is detected in testes. The study should include plasma exposure levels that meet/exceed the human exposure for NHC. Merck will submit the results of the PK study no later than March 31, 2022.
    - If the results of the PK study demonstrate NHC or NHC-TP distribution to testes, Merck will also conduct a male germ cell mutation assay in the Big Blue rat model. Merck must submit a protocol for the Big Blue rat assay no later than 30 days after the PK results are submitted to FDA, or by April 30, 2022. Results from the Big Blue rat assay will be submitted no later than July 31, 2023.

O. Merck must maintain a pregnancy surveillance program to collect information through telephone and online reporting of pregnancies and collect outcomes for individuals who are exposed to molnupiravir during pregnancy. Merck must submit to the Agency reports detailing any available exposure information and outcome(s) data on a monthly basis unless otherwise notified by FDA.

P. Merck and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Facilities to Whom Molnupiravir Is Distributed and Healthcare Providers Administering Molnupiravir

Q. Healthcare facilities and healthcare providers will ensure that they are aware of the Letter of Authorization, and the terms herein. Healthcare providers must provide and document that a copy of the authorized Fact Sheet for Patients and Caregivers has been provided, either through electronic means or hardcopy, to the patient or caregiver prior to prescribing molnupiravir.

R. Healthcare providers must inform patients or caregivers of the information detailed in the section *Mandatory Requirements for Administration of Molnupiravir Under Emergency Use Authorization* in the Fact Sheet for Healthcare Providers.

S. Molnupiravir may only be prescribed to a pregnant individual after the prescribing healthcare provider has completed the mandatory requirements on patient assessment, patient counseling, and documentation as described in the Fact Sheet for Healthcare Providers. See *Mandatory Requirements for Administration of Molnupiravir Under Emergency Use Authorization* in the Fact Sheet for Healthcare Providers.

T. Healthcare providers must inform and document that pregnant individuals who are prescribed molnupiravir have been made aware of Merck's pregnancy surveillance program as detailed in the authorized Fact Sheets. If the pregnant individual agrees to participate in the pregnancy surveillance program and allows the prescribing healthcare provider to disclose patient specific information to Merck, the prescribing healthcare provider must provide the patient's name and contact information to Merck at 1-877-888-4231 or pregnancyreporting.msd.com.

U. Healthcare facilities and healthcare providers receiving molnupiravir will track all medication errors and serious adverse events that are considered to be potentially attributable to molnupiravir use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports must state, "Molnupiravir use for COVID-19 under Emergency Use Authorization" at the beginning of the question "Describe Event" for further analysis. A copy of the completed FDA Form 3500 must also be provided to Merck per the instructions in the authorized labeling.

V. Healthcare facilities and healthcare providers will ensure that appropriate storage is maintained until the product is administered consistent with the terms of this letter and the authorized labeling.

W. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensing and administration of molnupiravir for the use authorized in this letter (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

X. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by Merck and/or FDA. Such records will be made available to Merck, HHS, and FDA for inspection upon request.

Y. Healthcare facilities and providers will report therapeutics information and utilization data as directed by HHS.

Conditions Related to Printed Matter, Advertising, and Promotion

Z. All descriptive printed matter, advertising, and promotional materials relating to the use of molnupiravir under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the Act, as applicable, and FDA implementing regulations. References to "approved labeling", "permitted labeling" or similar terms in these requirements shall be understood to refer to the authorized labeling for the use of molnupiravir under this authorization. In addition, such materials shall:

- Be tailored to the intended audience.
- Not take the form of reminder advertisements, as that term is described in 21 CFR 202.1(e)(2)(i), 21 CFR 200.200 and 21 CFR 201.100(f).
- Present the same risk information relating to the major side effects and contraindications concurrently in the audio and visual parts of the presentation for advertising and promotional materials in audio-visual format.
- Be accompanied by the authorized labeling, if the promotional materials are not subject to Section 502(n) of the Act.
- Be submitted to FDA accompanied by Form FDA-2253 at the time of initial dissemination or first use.

If the Agency notifies Merck that any descriptive printed matter, advertising or promotional materials do not meet the terms set forth in conditions Z through BB of this EUA, Merck must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency's notification. Furthermore, as part of its notification, the Agency may also require Merck to issue corrective communication(s).

AA. No descriptive printed matter, advertising, or promotional materials relating to the use of molnupiravir under this authorization may represent or suggest that molnupiravir is safe or effective when used for the treatment of COVID-19.

BB. All descriptive printed matter, advertising, and promotional material, relating to the use of molnupiravir under this authorization clearly and conspicuously shall state that:

- Molnupiravir has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate; and

- The emergency use of molnupiravir is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

Page 11 – Merck Sharp & Dohme Corp.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Dated: January 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02359 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Stem Cell Therapeutic Outcomes Database, OMB No. 0915–0310—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than March 7, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Extension.

Abstract: Given the rapid evolution of COVID–19 and its impact on those with compromised immune systems, it is imperative for the transplant community to continue collecting COVID–19 related data. Having access to COVID–19 vaccination status on blood stem cell recipients and understanding immune responses will assist with making informed decisions regarding direct clinical care. This will also inform critical policy decisions.

The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended, provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. It also maintains a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (*e.g.,* bone marrow, cord blood, or other such product) from a donor.

Given the rapid evolution of the COVID–19 public health emergency and its impact on immunocompromised patients, availability of new vaccines, and continual changes in vaccination recommendations, HRSA wants to leverage the required data collection platform of the Stem Cell Therapeutic Outcomes Database to obtain vaccine information for all US allogeneic hematopoietic stem cell transplant recipients.

A 60-day notice published in the **Federal Register**, 86 FR 67478 (November 26, 2021). There were no public comments.

Need and Proposed Use of the Information: To collect COVID–19 vaccine data, HRSA is requesting an extension of OMB's approval of both the Pre-Transplant Essential Data (Pre-TED) Form 2400 and Post-Transplant Essential Data (Post-TED) Form 2450. Collecting these data will help clinicians and policymakers to understand the landscape of vaccination among immunocompromised patients before and after a blood stem cell transplant.

This information will be used to analyze outcomes based on vaccine manufacturer/type, doses received (including potential boosters), timing, and inform future vaccination strategies. Information currently collected regarding COVID–19 infections has already been used in research studies.

Data collected prior to a patient receiving a blood stem cell transplant will be used to characterize frequencies of vaccination, and the level of protection afforded during and after transplant based on the incidence of COVID infection. Post-transplant, this information can be used to assess vaccination rates and timing in blood stem cell recipients, characterize emerging vaccination strategies (which may include ''boosters''), describe possible short and long-term side effects

of vaccines, and analyze the incidence of COVID–19 infection based on different vaccination approaches. This information may guide future vaccination strategies or COVID treatments. The vaccination status of recipients may also be useful for risk adjustment in the annual transplant center-specific analysis. For example, CDC advisors could potentially use COVID–19 vaccination data on blood stem cell transplant recipients to make informed decisions regarding whether to issue any recommendations for this medically vulnerable population. The data collected under this extension request could help answer these and other questions.

The additional COVID–19 vaccine questions capture basic information on vaccination status, vaccine manufacturer/type, dose(s) given, and date(s) received. Patients who need a blood stem cell transplant are typically aware of their COVID–19 risk and vaccination status, and the information is also found on the vaccine cards carried by most recipients. Questions about vaccination status will likely become universal at transplant center intake for the next 12 months or more. For these reasons, HRSA believes the data will be readily available to data professionals working at transplant centers via the medical record. To reduce burden, an ''unknown'' option has been included for scenarios where the data cannot be located, and a ''date estimated'' checkbox has been included when the exact date of vaccination is not known. Although these questions are anticipated to be asked over the next 12 months and then removed, other COVID–19 related questions may be requested for inclusion on these forms in the future given the rapid evolution of COVID–19 and its impact on immunocompromised patients, availability of new vaccines, and continual changes in vaccination recommendations.

Likely Respondents: Transplant Centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Form name	Number of respondents [1]	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Baseline Pre-Transplant Essential Data (TED)	200	48	9,600	[2] 0.70	6,720
Disease Classification	200	48	9,600	[3] 0.43	4,160
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	45	9,000	1.00	9,000
100-day Post-TED	200	48	9,600	0.88	8,448
6 month Post-TED	200	43	8,600	0.85	7,310
1 year Post-TED	200	40	8,000	0.65	5,200
2 year Post-TED	200	34	6,800	0.65	4,420
3+ years Post-TED	200	172	34,400	[4] 0.52	17,773
Total	200		95,600		63,031

[1] The total of 200 is the number of centers completing the form; the same group will complete all of the forms.
[2] The decimal is rounded up, and the actual number is .683333333.
[3] The decimal is rounded down, and the actual number is .433333333.
[4] The decimal is rounded up, and the actual number is .516667.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–02318 Filed 2–3–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information: Regarding a Revision to U.S. Public Health Service Guideline: Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: The Office of the Assistant Secretary for Health in the Department of Health and Human Services (HHS) seeks public comment regarding a proposed revision to the 2020 PHS Guideline Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection (1). The Organ Procurement and Transplantation Network (OPTN) implemented a policy change related to organ transplant candidate assessment and testing on March 1, 2021, to align OPTN policy with the new Guideline recommendations (2). Previous PHS Guideline recommendations did not include a specific timeframe during which pre-transplant testing for HIV, HBV, and HCV infections among organ transplant candidates should occur. In order to more accurately assess pre-transplant infection status and to enable the investigation of possible solid organ donor transmission of infection, the 2020 Guideline specified that pre-transplant HIV, HBV, and HCV testing of transplant candidates should occur during hospital admission for transplant

surgery but prior to the implantation of the organ. In May 2021, HHS reviewed communications from members of the public to the OPTN, outlining concerns that the additional amount of blood drawn for infectious disease testing (when added to the relatively large amount of blood required for immediate preoperative laboratory testing) during the admission for transplantation poses potential risks for some pediatric organ transplant candidates. Potential risks due to blood volume loss include those related to preoperative low body weight (and low blood volume), anemia, or exacerbation of underlying co-morbid conditions. HHS conducted a review of the most recent HIV, HBV, and HCV surveillance data in the United States as stratified by age group. Additionally, HHS engaged with relevant stakeholders during May–November 2021, to understand implications of policy changes on organ transplantation and organ utilization. In December 2021, findings from these analyses were presented to the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA). The committee considered whether a revision to the Guideline recommendation pertaining to pre-transplant testing of candidates ≤10 years of age is warranted. Based on feedback from the ACBTSA and analyses specified above, HHS is proposing changes pertinent to the timing of pre-transplant testing for candidates ≤10 years of age. HHS is asking respondents to review the proposed revision to the current Guideline (listed in the Supplementary Information section of this notice) and provide assessments on updating the Guideline, whether this change is achievable in the clinical setting, or if there are potential barriers to implementation. In addition, impact on organ allocation and utilization should be considered. Other comments pertinent to this proposed revision are welcome.

DATES: To be assured consideration, comments must be received at the address provided below no later than 5:00 p.m. ET on March 7, 2022.

ADDRESSES: Electronic responses are strongly preferred and may be addressed to *ACBTSA@hhs.gov.* Please include in the subject line of the email: ACBTSA–RFI.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Designated Federal Official, Office of Infectious Disease and HIV/AIDS Policy, 202–795–7608.

SUPPLEMENTARY INFORMATION:

Background: Since the emergence of the human immunodeficiency virus (HIV) epidemic in the 1980s, the U.S. Public Health Service (PHS) has made recommendations to reduce the risk of HIV transmission associated with organ transplantation (3, 4). Historically, recommendations included identifying risk factors among organ donors associated with HIV infection to minimize risk of potential transmission to recipients. Recommendations also included laboratory screening of donors using anti-HIV antibody testing, with additional testing recommendations added as technologies such as nucleic acid testing (NAT) were developed. In 2013, based on donor-derived transmission events and reports of poor recipient outcomes from hepatitis B virus (HBV) and hepatitis C virus (HCV) transmission, the PHS released a revised guideline. The 2013 Guideline added organ donor screening recommendations for HBV (hepatitis B surface antigen [HBsAg] and total antibody to hepatitis B core antigen [total anti-HBc]) and HCV (antibody to hepatitis C [anti-HCV] and HCV RNA by NAT), in addition to HIV, to reduce the risk of unintended transmission through transplantation (5). This revised Guideline was enhanced by recommending specific recipient informed consent and post-transplant recipient monitoring for evidence of possible disease transmission.

In 2020, the Guideline was updated to reflect changes in the epidemiology of HIV, HBV, and HCV infections, advances in testing, and the widespread availability of highly effective (for HIV and HBV) and curative (for HCV) treatment. In addition to several other updated recommendations, the 2020 Guideline specified that all transplant candidates should be tested prior to surgery for HIV, HBV, and HCV infections, with testing to occur during hospital admission for transplant but before transplantation (1). This recommendation was implemented in order to more accurately assess pre-transplant infection status and to enable the investigation of whether infectious disease transmission may have occurred through transplantation. Based on the feedback from members of the public that this requirement for repeat screening at the time of transplantation might pose potential harm to some pediatric patients due to blood volume loss, HHS (including CDC and HRSA) conducted additional analyses of surveillance data. Additionally, CDC and HRSA also participated in a work group convened by the OPTN and which included members of the OPTN Disease Transmission Advisory Committee and Pediatric Committee.

CDC surveillance data for the years 2015–2019 pertaining to incident HIV infections among pediatric populations in the United States were reviewed. Briefly, 524 children <13 years of age in the United States and 6 U.S. territories and freely associated states received a new diagnosis of HIV infection from 2015–2019. Overall, 181 (35%) of these 524 children received their diagnosis of HIV infection between 0–5 months of age; an additional 23 (4%) were diagnosed between 6–11 months of age. With effective perinatal elimination efforts, prevalence and incidence of HIV infection in children <13 years of age in the United States have been steadily decreasing (6). Children <13 years of age are among the lowest risk group for new HIV infections in the United States. Estimated prevalence of HIV infection in children <13 years of age in the United States is <2,000; incidence in this age group is <100 cases per year, and most of these are perinatally acquired (6). With perinatal testing and clinical follow-up of exposed children, it is unlikely that a transplant candidate ≤10 years of age would have an undiagnosed HIV infection at the time of organ transplantation.

CDC surveillance data for 2019 pertaining to incident HBV and HCV infections among pediatric populations in the United States were also reviewed. Incident HBV and HCV infections are similarly low among children in the United States. The rate of acute HBV infection in persons <20 years in the United States was 0.0 per 100,000 population as of 2019 (7). Additionally, more than 90% of 2-year-olds and adolescents in the United States have been vaccinated against HBV (8, 9). The rate of acute HCV infection in persons <20 years in the United States was 0.1 per 100,000 population as of 2019 (7). Perinatal exposure is the most common mode of transmission for HCV infection in children.

In December 2021, HHS convened the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) to receive expert input on whether, and if so, how, the current PHS Guideline recommendation pertaining to pre-transplant testing of pediatric candidates should be revised (*https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2021-12-01/index.html*). Additionally, HHS solicited input from this committee on the specific question as to whether available data support exempting solid organ transplant candidates who are ≤10 years of age at the time of transplant (and who have received postnatal infectious disease testing) from the recommendation for HIV, HBV, and HCV testing during hospital admission

for transplant but prior to anastomosis of the first organ. The committee voted unanimously in favor of the change.

Potential revision to the 2020 Guideline: HHS has reviewed the ACBTSA recommendations and other available information and is considering the following revision to current recommendations in the 2020 Guideline.

Exempt solid organ transplant candidates who are ≤10 years of age at the time of transplant (and who have received postnatal infectious disease testing) from the recommendation for HIV, hepatitis B virus, and hepatitis C virus testing during the hospital admission for transplant but prior to anastomosis of the first organ.

HHS is not considering changes to any other 2020 Guideline recommendations. We seek informed feedback regarding this proposed change to the recommendations in the 2020 Guideline.

Dated: January 25, 2022.

James J. Berger,

Designated Federal Officer, Advisory Committee on Blood and Tissue Safety and Availability, Office of Infectious Disease and HIV/AIDS Policy.

Footnotes

1. Jones JM, Kracalik I, Levi ME, et al. Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection—U.S. Public Health Service Guideline, 2020. MMWR Recomm Rep 2020;69(No. RR–4):1–16. DOI: *http://dx.doi.org/10.15585/mmwr.rr6904a1*.
2. OPTN *Policy 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements.* Available: *https://optn.transplant.hrsa.gov/media/eavh5bf3/optn-policies-effective-as-of-dec-6-2021-e-signature.pdf*.
3. CDC. Guidelines for preventing transmission of human immunodeficiency virus through transplantation of human tissue and organs. Centers for Disease Control and Prevention. MMWR Recommendations and reports: Morbidity and mortality weekly report Recommendations and reports/Centers for Disease Control. 1994;43(RR–8):1–17.
4. CDC. Testing donors of organs, tissues, and semen for antibody to human T-lymphotropic virus type III/lymphadenopathy-associated virus. MMWR Morbidity and mortality weekly report. 1985;34(20):294.
5. Seem DL, Lee I, Umscheid CA, Kuehnert MJ. PHS guideline for reducing human immunodeficiency virus, hepatitis B virus, and hepatitis C virus transmission through organ transplantation. Public health reports (Washington, DC: 1974). 2013;128(4):247–343.
6. Centers for Disease Control and Prevention. *HIV Surveillance Report, 2019;* vol.32. *http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.* Published May 2021.
7. Centers for Disease Control and Prevention. 2019 Viral Hepatitis Surveillance Report. *https://www.cdc.gov/hepatitis/statistics/SurveillanceRpts.htm.* Published July 2021.
8. FastStats—Immunization (*cdc.gov*): *https://www.cdc.gov/nchs/fastats/immunize.htm.*
9. Elam-Evans LD, Yankey D, Singleton JA, et al. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years—United States, 2019. MMWR Morb Mortal Wkly Rep 2020;69:1109–1116. DOI: *http://dx.doi.org/10.15585/mmwr.mm6933a1*.

[FR Doc. 2022–02389 Filed 2–3–22; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Aging Systems and Geriatrics Study Section.

Date: March 3–4, 2022.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Inese Z. Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7892, Bethesda, MD 20892, 301–435–1034, *beitinsi@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Organization and Delivery of Health Services Study Section.

Date: March 3–4, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Catherine Hadeler Maulsby, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1266, *maulsbych@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–20–117: Maximizing Investigators' Research Award (MIRA) for Early Stage Investigators (R35—Clinical Trial Optional).

Date: March 8–9, 2022.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anita Szajek, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–6276, *anita.szajek@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery Involving the Nervous System.

Date: March 8–9, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lai Yee Leung, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1011D, Bethesda, MD 20892, (301) 435–1042, *leungl2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biomaterials, Delivery, and Nanotechnology.

Date: March 10–11, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181,

MSC 7892, Bethesda, MD 20892, 301–435–2902, *filpuladr@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Instrumentation, Environmental and Occupational Safety.

Date: March 10–11, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joonil Seog, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–9791, *joonil.seog@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: SBIR/STTR Commercialization Readiness Pilot (CRP) Program.

Date: March 10, 2022.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301–379–9351, *allen.richon@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Cancer Immunology and Immunotherapy.

Date: March 10–11, 2022.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7806, Bethesda, MD 20892, 301–451–4467, *howardz@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: March 10–11, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Reigh-Yi Lin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4152, MSC 7846, Bethesda, MD 20892, (301) 827–6009, *lin.reigh-yi@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–21–018: NIH Director's Early Independence Awards.

Date: March 10–11, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Skeletal Biology and Tissue Engineering.

Date: March 10, 2022.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

Date: March 10, 2022.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Richard D. Schneiderman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, Bethesda, MD 20817, 301–402–3995, *richard.schneiderman@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Gut Inflammation and Microbiome.

Date: March 11, 2022.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ganesan Ramesh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 827–5467, *ganesan.ramesh@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 31, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02347 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIGMS Initial Review Group Training and Workforce Development Study Section—B.

Date: March 11, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Video Meeting).

Contact Person: Stephanie L. Constant, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Research Activities, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301–443–8784, *constantsl@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated January 31, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02329 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel, MorPhiC.

Date: March 16, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Keith McKenney, Ph.D., Scientific Review Officer, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892, 301–594–4280, *mckenneyk@mail.nih.gov*.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel, Advancing Genomic Medicine.

Date: March 17, 2022.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rudy O. Pozzatti, Ph.D, Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892, (301) 594–4280, *pozzattr@mail.nih.gov*.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel, Single Molecule Protein Sequencing.

Date: March 18, 2022.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rudy O. Pozzatti, Ph.D, Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892, (301) 594–4280, *pozzattr@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: January 31, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02332 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Clinical Trials SEP (UG3, U24, R61, R34).

Date: March 10, 2022.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Zhihong Shan, MD, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205–J, Bethesda, MD 20892, (301) 827–7085, *zhihong.shan@nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Regenerative Medicine Innovation Project Review.

Date: March 11, 2022.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–Z, Bethesda, MD 20892, (301) 827–7975, *reillymp@nhlbi.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Understanding and Reducing Cardiovascular Disease in Type 1 Diabetes Mellitus.

Date: March 30, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–Z, Bethesda, MD 20892, (301) 827–7987, *susan.sunnarborg@nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Stimulating Access to Research in Residency Transition Scholar.

Date: March 30, 2022.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Zhihong Shan, MD, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205–J, Bethesda, MD 20892, (301) 827–7085, *zhihong.shan@nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Syndemics of HLBS Diseases and HIV.

Date: March 31, 2022.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Shelley Sehnert, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 208–T, Bethesda, MD 20817, (301) 827–7984, *ssehnert@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 31, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02333 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Clinical Oncology Study Section.
Date: February 28–March 1, 2022.
Time: 9:00 a.m. to 8:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Laura Asnaghi, Ph.D., Scientific Review Officer, National Institute of Health, Center for Scientific Review, 6701 Rockville Drive, Room 6200, MSC 7804, Bethesda, MD 20892, (301) 443–1196, *laura.asnaghi@nih.gov*.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Healthcare and Health Disparities Study Section.
Date: March 3–4, 2022.
Time: 9:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Jessica Bellinger, Ph.D., Scientific Review Officer, Center for Scientific of Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, 301–827–4446, *bellingerjd@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Risks, Prevention and Health Behavior.
Date: March 3–4, 2022.
Time: 9:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Martha M. Faraday, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 435–3575, *faradaym@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Lifestyle Change and Behavioral Health Study Section.
Date: March 3–4, 2022.
Time: 9:30 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Pamela Jeter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 10J08, Bethesda, MD 20892, (301) 827–6401, *pamela.jeter@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR21–326: Modern Equipment for Shared-Use Biomedical Research Facilities: Advancing Research-Related Operations.
Date: March 3–4, 2022.
Time: 10:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Jonathan Michael Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *jonathan.peterson@nih.gov*.

Name of Committee: Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.
Date: March 3–4, 2022.
Time: 10:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Motivated Behavior, Alcohol and Neurotoxicology.
Date: March 9, 2022.
Time: 11:00 a.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *selmanom@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Pain, Chemosensation and Sensory Motor Neurobiology.
Date: March 10, 2022.
Time: 10:30 a.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Roger Janz, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–8515, *janzr2@csr.nih.gov*.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; HIV Molecular Virology, Cell Biology, and Drug Development Study Section.
Date: March 14–15, 2022.
Time: 10:00 a.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@csr.nih.gov*.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; HIV Comorbidities and Clinical Studies Study Section.
Date: March 15–16, 2022.
Time: 9:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: David C. Chang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 451–0290, *changdac@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 31, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02330 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Initial Review Group Genome Research Study Section.
Date: March 3, 2022.
Time: 11:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Keith McKenney, Ph.D, Scientific Review Officer, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20817, 301–594–4280, *mckenneyk@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: January 31, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02331 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Centers for HIV Structural Biology (U54 Clinical Trial Not Allowed).

Date: March 2–3, 2022.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: J. Bruce Sundstrom, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11A, Rockville, MD 20892, 240–669–5045, *sundstromj@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 31, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02346 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Frederick National Laboratory Advisory Committee to the National Cancer Institute.

The meeting will be held virtually and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

Name of Committee: Frederick National Laboratory Advisory Committee to the National Cancer Institute.

Date: February 24, 2022.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: Ongoing and new activities at the Frederick National Laboratory for Cancer Research.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Contact Person: Wlodek Lopaczynski, M.D., Ph.D., Assistant Director, Office of the Director, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Seventh Floor, West Tower, Room 7W514, Bethesda, MD 20892, (240) 276–6458, *lopacw@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: FNLAC: *https://deainfo.nci.nih.gov/advisory/fac/fac.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 1, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02367 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, March 23, 2022, 11:30 a.m. to March 23, 2022, 02:30 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, which was published in the **Federal Register** on December 28, 2021, FR Doc. 2021–28091, 86 FR 73792.

The meeting notice is amended to change the Contact Person from: Anita H. Undale, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–827–7428, *anita.undale@nih.gov* to Bita Nakhai, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7701, *nakhaib@nia.nih.gov.* The meeting is closed to the public. The meeting is closed to the public.

Dated: January 31, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02334 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Initial Review Group; Mental Health Services Study Section.

Date: March 3–4, 2022.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Room 6136, MSC 9606, Bethesda, MD 20852, 301–443–1225, *aschulte@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: February 1, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02373 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD) Consortium Review Panel (RFA AA 21–010,011,012,013,14).

Date: March 31, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Philippe Marmillot, Ph.D., Scientific Review Officer, Extramural Project Review Branch, 6700 B Rockledge Drive, Room 2118, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD 20892, (301) 443–2861, *marmillotp@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: February 1, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02362 Filed 2–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting for the Interdepartmental Substance Use Disorders Coordinating Committee (ISUDCC)

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (Secretary) announces a meeting of the Interdepartmental Substance Use Disorders Coordinating Committee (ISUDCC).

The ISUDCC is open to the public and members of the public can attend the meeting via telephone or webcast only, and not in person. Agenda with call-in information will be posted on the SAMHSA website prior to the meeting at: *https://www.samhsa.gov/about-us/advisory-councils/meetings.* The meeting will include information on establishing ISUDCC working groups support for the mission and work of the Committee; federal advances to address challenges in substance use disorder (SUD); and non-federal advances to address challenges in SUD.

Committee Name: Interdepartmental Substance Use Disorders Coordinating Committee (ISUDCC).

Date/Time/Type: March 16, 2022, 1:00 p.m.–4:00 p.m. (EDT)/Open.

ADDRESSES: The meeting will be held virtually.

The meeting can be accessed via Zoom.

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The Interdepartmental Substance Use Disorders Coordinating Committee is required under Section 7022 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, Pub. L. 115–271) to accomplish the following duties: (1) Identify areas for improved coordination of activities, if any, related to substance use disorders, including research, services, supports, and prevention activities across all relevant federal agencies; (2) identify and provide to the Secretary recommendations for improving federal programs for the prevention and treatment of, and recovery from, substance use disorders, including by expanding access to prevention, treatment, and recovery services; (3) analyze substance use disorder prevention and treatment strategies in different regions of and populations in the United States and evaluate the extent to which federal substance use disorder prevention and treatment strategies are aligned with State and local substance use disorder prevention and treatment strategies; (4) make recommendations to the Secretary regarding any appropriate changes with respect to the activities and strategies described in items (1) through (3) above; (5) make recommendations to the Secretary regarding public participation in decisions relating to substance use disorders and the process by which public feedback can be better integrated into such decisions; and (6) make recommendations to ensure that substance use disorder research, services, supports, and prevention activities of the Department of Health and Human Services and other federal agencies are not unnecessarily duplicative.

Not later than one year after the date of the enactment of this Act, and annually thereafter for the life of the Committee, the Committee shall publish on the internet website of the Department of Health and Human Services, which may include the public information dashboard established under section 1711 of the Public Health Service Act, as added by section 7021, a report summarizing the activities carried out by the Committee pursuant

to subsection (e), including any findings resulting from such activities.

II. Membership

This ISUDCC consists of federal members listed below or their designees, and non-federal public members.

Federal Membership: Members include, The Secretary of Health and Human Services; The Attorney General of the United States; The Secretary of Labor; The Secretary of Housing and Urban Development; The Secretary of Education; The Secretary of Veterans Affairs; The Commissioner of Social Security; The Assistant Secretary for Mental Health and Substance Use; The Director of National Drug Control Policy; representatives of other Federal agencies that support or conduct activities or programs related to substance use disorders, as determined appropriate by the Secretary.

Non-Federal Membership: Members include, 18 non-federal public members appointed by the Secretary, representing individuals who have received treatment for a diagnosis of a substance use disorder; directors of a State substance abuse agencies; representatives of a leading research, advocacy, or service organizations for adults with substance use disorder; physicians, licensed mental health professionals, advance practice registered nurses, and physician assistants, who have experience in treating individuals with substance use disorders; substance use disorder treatment professionals who provide treatment services at a certified opioid treatment program; substance use disorder treatment professionals who have research or clinical experience in working with racial and ethnic minority populations; substance use disorder treatment professionals who have research or clinical mental health experience in working with medically underserved populations; state-certified substance use disorder peer support specialists; drug court judge or a judge with experience in adjudicating cases related to substance use disorder; public safety officers with extensive experience in interacting with adults with a substance use disorder; and individuals with experiences providing services for homeless individuals with a substance use disorder.

The ISUDCC is required to meet at least twice per calendar year.

To attend virtually, submit written or brief oral comments, or request special accommodation for persons with disabilities, contact Tracy Goss. Individuals can also register on-line at: *https://snacregister.samhsa.gov/MeetingList.aspx.*

The public comment section will be scheduled at the conclusion of the meeting. Individuals interested in submitting a comment, must notify Tracy Goss on or before March 4, 2022 via email to: *Tracy.Goss@samhsa.hhs.gov.*

Up to three minutes will be allotted for each approved public comment as time permits. Written comments received in advance of the meeting will be considered for inclusion in the official record of the meeting.

Substantive meeting information and a roster of Committee members is available at the Committee's website: *https://www.samhsa.gov/about-us/advisory-councils/meetings.*

FOR FURTHER INFORMATION CONTACT: Tracy Goss, ISUDCC Designated Federal Officer, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, 13E37B, Rockville, MD 20857; telephone: 240–276–0759; email: *Tracy.Goss@samhsa.hhs.gov.*

Dated: February 1, 2022.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2022–02393 Filed 2–3–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4535–DR; Docket ID FEMA–2022–0001]

Wyoming; Amendment No. 8 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Wyoming (FEMA–4535–DR), dated April 11, 2020, and related determinations.

DATES: This change occurred on January 7, 2022.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Nancy J. Dragani, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Tammy L. Littrell as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2022–02241 Filed 2–3–22; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3577–EM; Docket ID FEMA–2021–0001]

Illinois; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Illinois (FEMA–3577–EM), dated December 13, 2021, and related determinations.

DATES: This amendment was issued December 23, 2021.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Illinois is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared an emergency by the President in his declaration of December 13, 2021.

Menard County for emergency protective measures (Category B), including direct

federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2022–02239 Filed 2–3–22; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. ICEB–2022–0002]

Privacy Act of 1974; System of Records

AGENCY: Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: Rescindment of a system of records notice.

SUMMARY: In accordance with the Privacy Act of 1974, the U.S. Department of Homeland Security (DHS)/U.S. Immigration and Customs Enforcement (ICE) is giving notice that it is rescinding the following DHS/ICE Privacy Act system of records notices, ''DHS/ICE–005 Trade Transparency and Research System of Records'' and ''DHS/ICE–016 FALCON Search and Analysis System of Records'' and has consolidated both system of record notices into ''DHS/ICE–018 Analytical Records System of Records.''

DATES: These changes will be effective upon publication.

ADDRESSES: You may submit comments, identified by docket number ICEB–2022–0002 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Lynn Parker Dupree, Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528–0655.

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Jordan Holz, Privacy Officer, *ICEPrivacy@ice.dhs.gov,* U.S. Immigration and Customs Enforcement (ICE), 500 12th Street SW, Mail Stop 5004, Washington, DC 20536, (202) 732–3300. For privacy questions, please contact: Lynn Parker Dupree, (202) 343–1717, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Privacy Act of 1974, 5 U.S.C. 552a, and as part of its ongoing integration and management efforts, the U.S. Department of Homeland Security (DHS) is rescinding the following system of records notices (SORN), ''DHS/U.S. Immigration and Customs Enforcement (ICE)–005 Trade Transparency and Research (TTAR)'' 79 FR 71112 (December 1, 2014) and ''DHS/ICE–016 FALCON-Search and Analysis'' 82 FR 20905 (May 4, 2017), and replace them with ''DHS/ICE–018 Analytical Records'' 86 FR 15246 (March 22, 2021). ICE will rely upon the DHS/ICE–018 Analytical Records SORN for records collected and maintained to support ICE's law enforcement mission. Eliminating these notices will have no adverse impacts on individuals, but will promote the overall streamlining and management of DHS Privacy Act record systems.

SYSTEM NAME AND NUMBER:

DHS/ICE–005 Trade Transparency Analysis and Research; DHS/ICE–016 FALCON Search and Analysis.

HISTORY:

DHS/ICE–005 Trade Transparency Analysis and Research, 79 FR 71112 (December 1, 2014), 77 FR 53893 (September 4, 2012), 73 FR 64967 (October 31, 2008); DHS/ICE–016 FALCON Search and Analysis, 82 FR 20905 (May 4, 2017).

* * * * *

Lynn P. Dupree,

Chief Privacy Officer, U.S. Department of Homeland Security.

[FR Doc. 2022–02323 Filed 2–3–22; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX21GW00SDRM100; OMB Control Number 1028–NEW]

Agency Information Collection Activities; Susquehanna River Angler Survey

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, we, the U.S. Geological Survey (USGS), are conducting a new information collection.

DATES: Interested persons are invited to submit comments on or before April 5, 2022.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–NEW in the subject line of your mail or email.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Christopher Huber email at *chuber@usgs.gov* or by telephone at 970–226–9219. Individuals who are hearing- or speech-impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the PRA of 1995 and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Whether this collection is necessary to the proper performance of the functions of the USGS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how the USGS might enhance the quality, utility, and clarity of the information to be collected; and (5) how the USGS might minimize the burden of this collection

on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other 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.

Abstract: The Susquehanna River Angler Survey collects information from anglers in Pennsylvania about their preferences for fishing, including information about their general fishing preferences, their most recent fishing trip, if they would have gone on their most recent fishing trip under different circumstances, and demographic information. The survey results will be used to determine the economic value of recreational fishing in the Susquehanna River and its tributaries under various best-management scenarios. The results will inform resource managers in considering the costs and benefits of alternative management actions.

Title of Collection: Susquehanna River Angler Survey.

OMB Control Number: 1028–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Individuals.

Total Estimated Number of Annual Respondents: 3,100.

Total Estimated Number of Annual Responses: 3,100.

Estimated Completion Time per Response: 15 minutes.

Total Estimated Number of Annual Burden Hours: 775.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Emily Pindilli,

Director, Science and Decisions Center.

[FR Doc. 2022–02417 Filed 2–3–22; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVL0000.L16100000.DP0000, N–96543 MO #4500156699]

Notice of Intent/Notice of Realty Action: Proposed Resource Management Plan Amendment and an Associated Environmental Assessment for the Direct Sale of 0.66 Acres in the Ely District Office, White Pine County, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action and notice of intent.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA) of 1969, as amended, and the Federal Land Policy and Management Act (FLPMA) of 1976, as amended, the Bureau of Land Management (BLM) Ely District Office, Ely, Nevada, intends to prepare a Resource Management Plan (RMP) amendment (RMPA), with an associated Environmental Assessment (EA), to the 2008 Ely District Record of Decision and Approved RMP. The proposed RMPA would evaluate whether the subject parcel of public land meets the disposal criteria described in Section 203 of the FLPMA, as amended, and allow the direct sale (without competition) of 0.66 acres of BLM managed public land to Nina Higgs, Trustee for Shirley Schena, if the parcel is determined to meet the disposal criteria. The purpose of the sale would be to resolve an inadvertent trespass and the EA would analyze the environmental effects of the direct sale of the land identified for disposal. The sale would be for no less than the appraised fair market value of $10,000. The sale would be subject to the applicable provisions of Section 203 of FLPMA and the BLM land sale regulations. Section 203 of FLPMA states that tracts of public land may be sold because of land use planning required under Section 202 of FLPMA; the subject parcel was not previously identified for disposal in the RMP, therefore the BLM must amend the RMP to allow the proposed sale to proceed. This notice serves to notify the public of the BLM's proposed realty action and initiates the public scoping process to solicit public comments on anticipated issues and planning criteria.

DATES: Interested parties may submit written comments regarding the RMPA planning criteria and proposed land sale during the 45-day scoping and comment period initiated by publication of this notice in the **Federal Register** and ending on March 21, 2022. All timely comments will be considered during analysis of the RMPA and land sale proposal. Interested parties will have the following additional opportunities to participate in this process:

Interested parties will be notified when the Draft RMPA, EA, and unsigned Finding of No Significant Impact (FONSI) are ready for review and will be provided another 30-day comment period. Upon review of comments to the Draft RMPA, EA, and unsigned FONSI, a Proposed RMPA, EA, and signed FONSI will be completed. Interested parties will be notified again when the Proposed RMPA, EA, and signed FONSI are ready for review which will initiate three, separate external engagement opportunities. First, interested parties will be provided a 30-day protest period, subject to 43 CFR 1610.5–2, on the Proposed RMPA to the BLM Nevada State Director. The BLM Nevada State Director will review all protests and must render land use planning decisions, which shall be the final decisions for the Department of the Interior (43 CFR 1610.5–2(b)). Second, the notification will also begin a separate, concurrent 60-day Governor's consistency review of the Proposed RMPA (43 CFR 1610.3–2(e)). The BLM Nevada State Director may negotiate a shorter Governor's consistency review period. The BLM Nevada State Director will review any inconsistencies with state plans, policies, or programs raised by the Governor and accept or reject recommendations proposed to resolve the inconsistencies. Any rejection of the recommendations will further initiate a 30-day appeal period for the Governor on the BLM Nevada State Director's rejection of the recommendations. Third, the notification of the Proposed RMPA, EA, and signed FONSI will also begin a separate, concurrent 30-day protest period subject to MS2711.4(d) on the land sale decision. The BLM Nevada State Director will review all protests and may sustain, vacate, or modify the Proposed RMPA and land sale, in whole or in part. In the absence of any protests, the BLM will develop the approved RMPA and Decision Record, which will document the final determination of the Department of the Interior for the land sale. In addition to publication in the **Federal Register**, the BLM will publish this notice in the *Ely Times* newspaper once a week for three consecutive weeks. Any other subsequent notices related to the RMPA and land sale may also be published in the *Ely Times* newspaper.

ADDRESSES: Comments concerning the realty action and issues and planning criteria related to the RMPA, EA, and direct sale may be submitted by mail to: BLM, Bristlecone Field Office, 702 North Industrial Way, Ely, Nevada 89301, ATTN: Jared Bybee, Field Manager.

FOR FURTHER INFORMATION CONTACT: Nicole Cummings, Realty Specialist, Ely District Office, at 775–289–1809, or by email at *ncummings@blm.gov*; or Jared Bybee, Field Manager, Bristlecone Field Office, at 775–289–1847, or by email at *jbybee@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours. Project information, documents, and associated maps will be available for review during associated public comment and review periods during business hours, Monday through Friday, at the Bristlecone Field Office, except during Federally recognized holidays. Project information will also be available on the BLM's e-Planning website: *https://go.usa.gov/xMDeX.*

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM Ely District Office, Ely, Nevada, proposes to segregate the identified public land, amend the relevant RMP, and prepare an associated EA that proposes to offer the land for direct sale to resolve the issue of an inadvertent trespass. The BLM will examine the following described public lands located in White Pine County, Nevada, for disposal suitability under the authority of Sections 202 and 203 of FLPMA:

Mount Diablo Meridian, Nevada

T. 14 N., R. 70 E.,
Sec. 19, lot 20.

The area described contains 0.66 acres, according to the official plats of the said land, on file with the BLM.

Upon publication of this Notice in the **Federal Register**, the public land described above will be segregated from all forms of appropriation under the public land laws, including the mining laws, except for the sale provisions of the FLPMA. The segregation will terminate upon (1) issuance of a conveyance document; (2) publication in the **Federal Register** terminating the segregation; or (3) two years from publication of this notice, unless extended by the BLM Nevada State Director in accordance with 43 CFR 2711.1–2(d). Until completion of the sale, the BLM will no longer accept land use applications affecting the identified public land in accordance with 43 CFR 2807.15.

The BLM may sell a tract of public land because of approved land use planning if the sale of the tract meets the disposal criteria. The 2008 Ely District Record of Decision and Approved RMP does not identify the 0.66 acres of public land in question as suitable for disposal. Therefore, to dispose of the tract, the BLM must amend the RMP to meet the requirements of FLPMA Section 203 through land use planning. If authorized, the underlying decision will amend the 2008 Ely District RMP, establishing that ''such tract, because of its location or other characteristics, is difficult and uneconomic to manage as part of the public lands and is not suitable for management by another Federal department or agency.''

The BLM will analyze the parcel and develop an EA to evaluate the environmental effects of the proposed RMPA and the sale criteria under FLPMA Section 203(a)(3) and 43 CFR 2710.0–3(a)(3) to ensure the disposal of the tract will serve important public objectives, including but not limited to relieving BLM authority for a parcel of public land that, because of its location or other characteristics, is difficult and uneconomic to manage as part of the public lands and is not suitable for management by another Federal department or agency. After the BLM has analyzed public scoping comments and prepared the analysis, the EA will be available for a 30-day protest period.

The parcel being considered for direct sale is not required for any other Federal purpose. Regulations contained in 43 CFR 2710.0–6(c)(3)(iii) and 2711.3–3(a)(5) make allowances for direct sales to resolve inadvertent unauthorized use or occupancy of public land. The BLM will consider selling this parcel if it is determined that the public interest would best be served by selling the 0.66-acre parcel to Nina Higgs, Trustee for Shirley Schena, for the fair market value of at least $10,000 to resolve the inadvertent trespass and ensure the federal government receives fair compensation for the sale of the parcel. The BLM has determined the parcel is not an access point for recreation in accordance with Secretary's Order 3373, *Evaluating Public Access in Bureau of Land Management Public Land Disposals and Exchanges.* Disposal of this tract will have no anticipated impacts on recreational access to adjacent tracts of publicly accessible lands.

The conveyance document, if issued, will contain the following reservations, excepting and reserving to the United States:

(1) A right-of way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945);

(2) All the mineral deposits in the land so patented pursuant to the Act of October 21, 1976 (43 U.S.C. 1719), including, without limitation, substances subject to disposition under the general mining laws, the general mineral leasing laws, the Materials Act and the Geothermal Steam Act, and to it, its permittees, licensees, lessees, and mining claimants, the right to prospect for, mine, and remove the minerals owned by the United States under applicable law and such regulations as the Secretary of the Interior may prescribe. This reservation includes necessary access and exit rights and the right to conduct all necessary and incidental activities including, without limitation, all drilling, underground, open pit or surface mining operations, storage, and transportation facilities deemed reasonably necessary.

Unless otherwise provided by separate agreement with the surface owner, mining claimants, permittees, licensees, and lessees of the United States shall reclaim disturbed areas to the extent prescribed by regulations issued by the Secretary of the Interior.

All causes of action brought to enforce the rights of the surface owner under the regulations above referred to shall be instituted against mining claimants, permittees, licensees, and lessees of the United States; and the United States shall not be liable for the acts or omissions of its mining claimants, permittees, licensees, and lessees.

(3) An appropriate indemnification clause protecting the United States from claims arising out of the patentee's use, occupancy, or occupation on the patented lands.

The conveyance document, if issued, will be subject to all valid existing rights. The BLM will publish this notice in the *Ely Times* newspaper once a week for three consecutive weeks. Comments will be accepted as discussed in the **ADDRESSES** section above.

Any adverse comments regarding the sale will be reviewed by the BLM Nevada State Director or other authorized official of the Department of the Interior, who may sustain, vacate, or modify this realty action in response to such comments. In the absence of comments, this realty action will

become the final determination of the Department of the Interior.

This document also announces the beginning of the scoping process and seeks public input on preliminary issues and planning criteria. The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the planning process. The following preliminary issues and planning criteria for the plan amendment have been identified by BLM personnel:

Preliminary Issues—(1) What impacts would the proposed sale have on resources potentially eligible for the National Register of Historic Places; (2) How would lands and realty be impacted or impact the proposed sale; and (3) What impacts would the proposed sale have on fish and wildlife, special status species, and migratory birds and their habitat? *Preliminary Planning Criteria*—(1) The Proposed RMP Amendment and associated EA will be in compliance with the FLPMA and all other applicable laws, regulations and policies; (2) the Proposed RMP Amendment will be in compliance with 43 CFR part 2711.3–3; (3) Impacts of the proposed direct land sale and RMP Amendment will be analyzed in an EA, in accordance with 43 CFR part 1500 and 43 CFR part 1600; (4) the EA and RMP Amendment will be developed in a manner consistent as possible with plans and policies of adjacent local, state, Tribal, and Federal agencies, within the parameters set by Federal laws, regulations, and policies; and (5) All data and graphic material in this plan amendment will be displayed electronically, using Geographic Information System (GIS) format. All applicable BLM data standards will be followed.

The BLM will evaluate identified issues to be addressed in the RMP Amendment and will place them into one of three categories: (1) Issues to be resolved in the plan amendment; (2) Issues to be resolved through policy or administrative action; or (3) Issues beyond the scope of this plan amendment.

The BLM will provide an explanation in the Draft/Preliminary EA as to why an issue was placed in Category Two or Three. The BLM will use an interdisciplinary approach to develop the RMPA and EA and consider the variety of resource issues and concerns identified. Additionally, the BLM or the Tribes can initiate, at any time during this process, consultation on a government-to-government basis in accordance with Executive Order 13175 and other policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration and will be analyzed in the EA.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 CFR subpart 1500; 43 CFR subpart 1600; 43 CFR 2710; 43 CFR 2711)

Robbie McAboy,

District Manager, Ely District Office.

[FR Doc. 2022–01396 Filed 2–3–22; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT929000–223–L14400000.BK0000; MO# 4500160249]

Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of surveys for the lands described in this notice are scheduled to be officially filed in the Bureau of Land Management (BLM) Montana State Office, Billings, Montana, 30 calendar days from the date of this publication. The surveys, which were executed at the request of the BLM Billings Field Office are necessary for the management of these lands.

DATES: A person or party who wishes to protest this decision must file a notice of protest in time for it to be received in the BLM Montana State Office no later than March 7, 2022.

ADDRESSES: You may submit written protests to the BLM Montana State Office, 5001 Southgate Drive, Billings, Montana 59101. A copy of the plats may be obtained from the Public Room at this same location upon required payment. The plats may be viewed at no cost.

FOR FURTHER INFORMATION CONTACT: Sonja (Suzie) Sparks, BLM Acting Chief Cadastral Surveyor for Montana; telephone: (307) 775–6225; email: *s75spark@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact Ms. Sparks during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

Principal Meridian, Montana

T. 3 S., R. 24 E.
Sec. 21.

A person or party who wishes to protest an official filing of a plat of survey identified above must file a written notice of protest with the BLM Chief Cadastral Surveyor for Montana at the address listed in the **ADDRESSES** section of this notice. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be received in the BLM Montana State Office no later than the scheduled date of the proposed official filing for the plat(s) of survey being protested; if received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of the protest, if not filed with the notice of protest, must be filed with the BLM Chief Cadastral Surveyor for Montana within 30 calendar days after the notice of protest is received.

If a notice of protest of the plat(s) of survey is received prior to the scheduled date of official filing or during the 10-calendar-day grace period provided in 43 CFR 4.401(a) and the delay in filing is waived, the official filing of the plat(s) of survey identified in the notice of protest will be stayed pending consideration of the protest. Upon receipt of a timely protest, and after a review of the protest, the Authorized Officer will issue a decision either dismissing or otherwise resolving the protest. A plat of survey will then be officially filed 30 days after the protest decision has been issued in accordance with 43 CFR part 4.

If a notice of protest is received after the scheduled date of official filing and the 10-calendar-day grace period provided in 43 CFR 4.401(a), the notice of protest will be untimely, may not be considered, and may be dismissed.

Before including your address, phone number, email address, or other personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we

cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C. chapter 3)

Sonja S. Sparks,

Acting Chief Cadastral Surveyor for Montana.

[FR Doc. 2022–02395 Filed 2–3–22; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORL00000.L18200000.XZ0000. LXSS020H0000.223.HAG 22–0008]

Notice of Public Meetings for the Southeast Oregon Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior Bureau of Land Management's (BLM) Southeast Oregon Resource Advisory Council (RAC) will meet as follows.

DATES: The Southeast Oregon RAC will meet on Wednesday, June 22, 2022, from 1 p.m. to 5 p.m. Pacific Time (PT) and on Thursday, June 23, from 8 a.m. to 12 noon PT.

The RAC will meet again on Wednesday, October 19, 2022, from 1 p.m. to 5 p.m. PT, and on Thursday, October 20, from 8 a.m. to 12 noon PT.

A public comment period will be offered at the end of each day's meeting.

ADDRESSES: Both the June and October meetings will be held virtually through the Zoom meeting application. Participation information and the final agenda will be available 30 days in advance of the meeting and will be posted online at *www.blm.gov/get-involved/resource-advisory-council/near-you/oregon-washington/southeast-oregon-rac.*

Comments can be mailed to: BLM Lakeview District; Attn: Todd Forbes, 1301 South G Street, Lakeview, OR 97630 or emailed to Lisa McNee at *lmcnee@blm.gov.* All comments received will be provided to the Southeast Oregon RAC members.

FOR FURTHER INFORMATION CONTACT: Lisa McNee, Public Affairs Specialist, 1301 South G Street, Lakeview, Oregon 97630; telephone: (541) 947–6811; email: *lmcnee@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact Lisa McNee during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Southeast Oregon RAC is chartered, and its 15 members are appointed by the Secretary of the Interior. Their diverse perspectives are represented in commodity, non-commodity, and local interests. The RAC serves in an advisory capacity to BLM and U.S. Forest Service (USFS) officials concerning planning and management of public land and national forest resources located, in whole or in part, within the boundaries of the BLM's Vale District, Burns District and Lakeview District and of the USFS's Fremont-Winema and Malheur National Forests. All meetings are open to the public in their entirety. The public should provide any information that it wishes to distribute to the RAC before the start of each meeting.

Both the June and October meetings will include updates and opportunities for RAC input regarding the Southeast Oregon and Lakeview Resource Management Plan Amendment processes; discussion on rangeland, grazing, and wild horse and burro herd management areas; review of and recommendations regarding proposed actions by the Burns, Vale, or Lakeview BLM Districts; and any other business that may reasonably come before the RAC. At the June meeting, the RAC will discuss commercial and dispersed recreation and opportunities for maintaining and enhancing public land access. Topics for the October meeting include discussions on programmatic environmental impact statements and categorical exclusions and how they relate to land management in eastern Oregon.

As noted earlier (see **DATES**), the public may address the Southeast Oregon RAC during the public comment portion of the meeting on June 22 and 23, 2022, and October 19 and 20, 2022. Depending on the number of persons wishing to speak, the time for individual comments may be limited.

Before including your address, phone number, email address, or other personal identifying information in your comments, please be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee we will be able to do so.

(Authority: 43 CFR 1784.4–2)

James Forbes,

Lakeview District Manager.

[FR Doc. 2022–02397 Filed 2–3–22; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–GATE–33195; PPNEGATEB0, PPMVSCS1Z.Y00000]

Request for Nominations for the Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee

AGENCY: National Park Service, Interior.

ACTION: Request for nominations.

SUMMARY: The National Park Service (NPS), U.S. Department of the Interior, is requesting nominations for qualified persons to serve as members of the Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee (Committee).

DATES: Written nominations must be received by April 5, 2022.

ADDRESSES: Nominations should be sent to Daphne Yun, Public Affairs Specialist, U.S. Department of the Interior, National Park Service, Gateway National Recreation Area, Office of the Superintendent, 210 New York Avenue, Staten Island, New York 10305, or email *daphne_yun@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Daphne Yun, via telephone at (718) 815–3651.

SUPPLEMENTARY INFORMATION: The Committee was established by authority of the Secretary of the Interior under 54 U.S.C. 100906, and in accordance with the Federal Advisory Committee Act (5 U.S.C. appendix 1–16). The purpose of the Committee is to advise the Secretary of the Interior, through the Director of the NPS, on the development of a reuse plan and on matters relating to future uses of certain buildings at the Fort Hancock Historic District, located within the Sandy Hook Unit of Gateway National Recreation Area in New Jersey.

The Committee consists of representatives from among, but not limited to, the following interest groups, to represent a range of interests concerned with the management of Fort Hancock within the park and its impact on the local area: The natural resource community; the business community; the cultural resource community; the real estate community; the recreation community; the education community; the scientific community; and hospitality organizations. The

Committee will also include representatives from the following municipalities: Borough of Highlands, Borough of Sea Bright, Borough of Rumson, Middletown Township, Monmouth County Freeholders, and Borough of Monmouth Beach. We are currently seeking members to represent all categories, especially hospitality organizations, including tourism and recreation. Nominations should be typed and include a resume providing an adequate description of the nominee's qualifications, including information that establish their membership requirements and permit the Department to contact them. All documentation, including letters of recommendation, must be compiled and submitted in one complete package. All those interested in membership, including current members whose terms are expiring, must follow the same nomination process. Members may not appoint deputies or alternates.

Members of the Committee serve without compensation. However, while away from their homes or regular places of business in the performance of services for the Committee as approved by the NPS, members may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in Government service are allowed such expenses under section 5703 of title 5 of the United States Code.

Authority: 54 U.S.C. 100906.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2022–02419 Filed 2–3–22; 8:45 am]

BILLING CODE 4312–52–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Adjustment of Certain Dollar Amounts in the Bankruptcy Code

AGENCY: Judicial Conference of the United States.

ACTION: Notice of adjusted dollar amounts.

SUMMARY: Pursuant to the United States Code, certain dollar amounts are adjusted to reflect the change in the Consumer Price Index for All Urban Consumers for the most recent 3-year period ending immediately before January 1, 2022.

DATES: The dollar amounts are adjusted on April 1, 2022.

FOR FURTHER INFORMATION CONTACT: Gary D. Streeting, Senior Attorney, Judicial Programs Division, Administrative Office of the United States Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Room 4–122, Washington, DC 20544, Telephone (202) 502–1800, or by email at *Judicial_Services_Office@ao.uscourts.gov.*

SUPPLEMENTARY INFORMATION: Section 104 of title 11, United States Code, provides the mechanism for an automatic three-year adjustment of dollar amounts in certain sections of titles 11 and 28. Notice is hereby given, pursuant to 11 U.S.C. 104(b), that the next such adjustment will occur on April 1, 2022. Effective on that date, the dollar amounts in effect under sections 101(3), 101(18), 101(19A), 101(51D), 109(e), 303(b), 507(a), 522(d), 522(f)(3) and 522(f)(4), 522(n), 522(p), 522(q), 523(a)(2)(C), 541(b), 547(c)(9), 707(b), 1322(d), 1325(b), and 1326(b)(3) of title 11, and section 1409(b) of title 28, United States Code, are adjusted as set forth in the chart below to reflect the change in the Consumer Price Index for All Urban Consumers, published by the Department of Labor, for the 3-year period ending immediately before January 1, 2022, rounded to the nearest $25. This adjustment does not apply with respect to cases commenced before April 1, 2022. Seven Official Bankruptcy Forms (106C, 107, 122A–2, 122C–2, 201, 207, and 410) and two Director's Forms (2000 and 2830) will also be amended to reflect these adjusted dollar amounts.

(Authority: 11 U.S.C. 104.)

Dated: January 31, 2022.

Gary D. Streeting,

Senior Attorney, Judicial Programs Division.

Affected sections of Title 28 U.S.C. and the bankruptcy code	Dollar amount to be adjusted	New (adjusted) dollar amount [1]
28 U.S.C.		
Section 1409(b)—a trustee may commence a proceeding arising in or related to a case to recover:		
(1)—money judgment of or property worth less than	$1,375	$1,525.
(2)—a consumer debt less than	$20,450	$22,700.
(3)—a non-consumer debt against a non-insider less than	$25,000	$27,750.
11 U.S.C.		
Section 101(3)—definition of assisted person	$204,425	$226,850.
Section 101(18)—definition of family farmer	$10,000,000 (each time it appears).	$11,097,350 (each time it appears).
Section 101(19A)—definition of family fisherman	$2,044,225 (each time it appears)	$2,268,550 (each time it appears).
Section 101(51D)—definition of small business debtor	$2,725,625 (each time it appears)	$3,024,725 (each time it appears).
Section 109(e)—debt limits for individual filing bankruptcy under chapter 13.	$419,275 (each time it appears) ... $1,257,850 (each time it appears)	$465,275 (each time it appears). $1,395,875 (each time it appears).
Section 303(b)—minimum aggregate claims needed for the commencement of an involuntary chapter 7 or 11 petition.	$16,750 (each time it appears)	$18,600 (each time it appears).
Section 507(a)—priority expenses and claims:		
(1)—in paragraph (4)	$13,650	$15,150.
(2)—in paragraph (5)(B)(i)	$13,650	$15,150.
(3)—in paragraph (6)	$6,725	$7,475.
(4)—in paragraph (7)	$3,025	$3,350.
Section 522(d)—value of property exemptions allowed to the debtor:		
(1)—in paragraph (1)	$25,150	$27,900.
(2)—in paragraph (2)	$4,000	$4,450.
(3)—in paragraph (3)	$625	$700.
	$13,400	$14,875.
(4)—in paragraph (4)	$1,700	$1,875.
(5)—in paragraph (5)	$1,325	$1,475.
	$12,575	$13,950.

Affected sections of Title 28 U.S.C. and the bankruptcy code	Dollar amount to be adjusted	New (adjusted) dollar amount [1]
(6)—in paragraph (6)	$2,525	$2,800.
(7)—in paragraph (8)	$13,400	$14,875.
(8)—in paragraph (11)(D)	$25,150	$27,900.
Section 522(f)(3)—exception to lien avoidance under certain state laws.	$6,825	$7,575.
Section 522(f)(4)—items excluded from definition of household goods for lien avoidance purposes.	$725 (each time it appears)	$800 (each time it appears).
Section 522(n)—maximum aggregate value of assets in individual retirement accounts exempted.	$1,362,800	$1,512,350.
Section 522(p)—state homestead exemption, limit for interest acquired 1215 days before filing.	$170,350	$189,050.
Section 522(q)—state homestead exemption, limit under particular circumstances.	$170,350	$189,050.
Section 523(a)(2)(C)—exceptions to discharge—presumption of nondischargeability:		
(1)—in paragraph (i)(I)—consumer debts for luxury goods or services incurred ≤90 days before filing owed to a single creditor in the aggregate.	$725	$800.
(2)—in paragraph (i)(II)—certain cash advances obtained ≤70 days before filing, in the aggregate.	$1,000	$1,100.
Section 541(b)—certain property of the estate exclusion limits	$6,825 (each time it appears)	$7,575 (each time it appears).
Section 547(c)(9)—minimum preference avoidance value in cases with primarily non-consumer debts.	$6,825	$7,575.
Section 707(b)—dismissal of a chapter 7 case or conversion to chapter 11 or 13 (means test):		
(1)—in paragraph (2)(A)(i)(I)	$8,175	$9,075.
(2)—in paragraph (2)(A)(i)(II)	$13,650	$15,150.
(3)—in paragraph (2)(A)(ii)(IV)	$2,050	$2,275.
(4)—in paragraph (2)(B)(iv)(I)	$8,175	$9,075.
(5)—in paragraph (2)(B)(iv)(II)	$13,650	$15,150.
(6)—in paragraph (5)(B)	$1,375	$1,525.
(7)—in paragraph (6)(C)	$750	$825.
(8)—in paragraph (7)(A)(iii)	$750	$825.
Section 1322(d)—length of chapter 13 plan, current monthly income, 4+ household.	$750 (each time it appears)	$825 (each time it appears).
Section 1325(b)—confirmation of chapter 13 plan, current monthly income, 4+ household.	$750 (each time it appears)	$825 (each time it appears).
Section 1326(b)(3)—payments to former chapter 7 trustee	$25	$25.

[1] The New (Adjusted) Dollar Amounts reflect a 10.97347880254584 percent increase, rounded to the nearest $25.

[FR Doc. 2022–02299 Filed 2–3–22; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–NEW]

Agency Information Collection Activities, Proposed eCollection eComments Requested Extension Without Change, of a Previously Approved Collection, Office of the Victims' Rights Ombudsman Crime Victims Rights Act Complaint Form

AGENCY: Department of Justice, Executive Office for United States Attorneys.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for United States Attorneys, Office of the Victims' Rights Ombudsman, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until March 7, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* New information collection request.

2. *The Title of the Form/Collection:* Complaint Form.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* An agency form number is pending. The applicable component within the Department of Justice is the Executive Office for United States Attorneys,

Office of the Victims' Rights Ombudsman.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* General public.

Information is used to receive and investigate complaints filed by federal crime victims against Department employees who violated or failed to provide the rights established under the Crime Victims Rights Act of 2004, 18 U.S.C. 3771. Respondents are individuals.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 100 respondents will complete each form within approximately 45 minutes.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 75 total annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: February 1, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–02415 Filed 2–3–22; 8:45 am]

BILLING CODE 4410–07–P

DEPARTMENT OF LABOR

[Docket No. OSHA–2022–0002]

Occupational Safety and Health Administration National Advisory Committee on Occupational Safety and Health (NACOSH): Notice of Meeting

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of NACOSH meeting.

SUMMARY: The National Advisory Committee on Occupational Safety and Health (NACOSH) will meet February 22, 2022, by teleconference and WebEx. In conjunction with the committee meeting, the NACOSH Heat Injury and Illness Prevention Work Group will hold an initial meeting on February 25, 2022.

DATES:

NACOSH meeting: NACOSH will meet from 1:00 p.m. to 5:00 p.m., ET, Tuesday, February 22, 2022.

NACOSH Work Group meeting: The NACOSH Heat Injury and Illness Prevention Work Group will meet from 1:00 p.m. to 3:00 p.m., ET, Friday, February 25, 2022.

ADDRESSES:

Submission of comments and requests to speak at the NACOSH meeting: Submit comments and requests to speak at the NACOSH meeting by February 15, 2022, identified by the docket number for this **Federal Register** notice (Docket No. OSHA–2022–0002), using the following method:

Electronically: Comments and request to speak, including attachments, must be submitted electronically at: *http://www.regulations.gov,* the Federal eRulemaking Portal. Follow the online instructions for submitting comments.

Requests for special accommodations: Submit requests for special accommodations for the NACOSH meeting by February 15, 2022, to Ms. Carla Marcellus, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–1865; email: *marcellus.carla@dol.gov.*

Instructions: All submissions for the NACOSH meeting must include the agency name and the OSHA docket number for this **Federal Register** notice (Docket No. OSHA–2022–0002). OSHA will place comments and requests to speak, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates.

Docket: To read or download documents in the public docket for the NACOSH meeting, go to *http://www.regulations.gov.* All documents in the public docket are listed in the index; however, some documents (*e.g.,* copyrighted material) are not publicly available to read or download through *http://www.regulations.gov.* All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Participation in the NACOSH Work Group meeting: Members of the public may attend the NACOSH Work Group meeting. However, any participation by the public will be in listen-only mode. OSHA is not receiving public comments or requests to speak at the Work Group meeting.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general information about NACOSH: Ms. Lisa Long, Acting Deputy Director, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–2409; email: *long.lisa@dol.gov.*

Telecommunication requirements: For additional information about the telecommunication requirements for the meeting, please contact Ms. Carla Marcellus, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–1865; email: *marcellus.carla@dol.gov.*

For copies of this ***Federal Register*** *Notice:* Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This notice, as well as news releases and other relevant information, are also available at OSHA's web page at *www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

NACOSH was established by Section 7(a) of the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651, 656) to advise, consult with, and make recommendations to the Secretary of Labor and the Secretary of Health and Human Services on matters relating to the administration of the OSH Act. NACOSH is a continuing advisory committee of indefinite duration.

NACOSH operates in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2), its implementing regulations (41 CFR part 102–3), and OSHA's regulations on NACOSH (29 CFR 1912.5 and 29 CFR part 1912a).

The establishment of subcommittees and subgroups, such as the NACOSH Heat Injury and Illness Prevention Work Group, is contemplated by both the FACA's implementing regulations and OSHA's regulations on NACOSH (see, *e.g.,* 41 CFR 102–3.135; 29 CFR 1912a.13). The NACOSH Work Group will operate in accordance with the FACA and these regulations.

II. Meeting Information

NACOSH meeting: Attendance at the NACOSH meeting will be by teleconference and WebEx only. The teleconference dial-in number and passcode are as follows: Dial-in number: 1–800–779–1534; Passcode: 2969166 and the WebEx link is: *https://usdolee.webex.com/usdolee/onstage/g.php?MTID=e166e7a8eecd74858afbb6afca6a8d00a* and the meeting password is: Welcome!24. The tentative agenda will include agency updates from OSHA and the National Institute for Occupational Safety and Health (NIOSH), a discussion of OSHA's work

on heat illness prevention, and a discussion on risk-based safety.

NACOSH Work Group Meeting: The NACOSH Heat Injury and Illness Prevention Work Group will also be by teleconference and WebEx only and is open to the public. Members of the public will be able to observe and will be kept in listen-only mode. The teleconference dial-in number and passcode are as follows: Dial-in number: 1–800–779–8290; Passcode: 8130648 and the WebEx link is: *https://usdolee.webex.com/usdolee/onstage/g.php?MTID=e9dbee080b62061cecf30e01d32135c2e* and the meeting password is: Welcome!24.

The Work Group was established to help NACOSH respond to OSHA's request to provide recommendations on the agency's heat injury and illness prevention guidance and rulemaking activities. The Work Group will evaluate OSHA's heat illness and prevention guidance materials, develop recommendations for guidance materials, evaluate stakeholder input, and develop recommendations on potential elements of a proposed heat injury and illness prevention standard. It will then present its written findings and proposed recommendations to the full NACOSH committee for consideration. After deliberations, NACOSH will submit its recommendations to the Secretary of Labor.

Authority and Signature

Douglas L. Parker, Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice under the authority granted by 29 U.S.C. 655(b)(1) and 656(b), 5 U.S.C. app. 2, 29 CFR parts 1912 and 1912a, and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed at Washington, DC, on January 24, 2022.

Douglas L. Parker,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2022–02379 Filed 2–3–22; 8:45 am]

BILLING CODE 4510–26–P

LEGAL SERVICES CORPORATION

2022 LSC Technology Initiative Grant Funding Notice

AGENCY: Legal Services Corporation (LSC).

ACTION: Notice.

SUMMARY: The Legal Services Corporation issues this Notice describing the conditions for submitting a Pre-Application for 2022 Technology Initiative Grants.

DATES: Pre-Applications must be submitted by 11:59 p.m. EST on Friday, March 18, 2021.

ADDRESSES: Pre-Applications must be submitted electronically to *https://grantease.lsc.gov/.*

FOR FURTHER INFORMATION CONTACT: David Bonebrake, Program Counsel, Office of Program Performance, Legal Services Corporation, 3333 K Street NW, Washington, DC 20007; (202) 295–1547 or *dbonebrake@lsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

Since 2000, Congress has provided an annual appropriation to LSC to award special funding for client self-help and information technology projects. LSC's Technology Initiative Grant (TIG) program funds technology tools that help achieve LSC's goal of increasing the quantity and quality of legal services available to eligible persons. Projects funded under the TIG program develop, test, and replicate innovative technologies that can enable grant recipients and state justice communities to improve low-income persons' access to high-quality legal assistance through an integrated and well-managed technology system. The TIG program also supports effective technology planning and management at LSC-funded organizations through the use of targeted assessment grants focused on improvements to technology systems and information security.

II. Funding Opportunities Information

A. Eligible Applicants

To be eligible for Technology Initiative Grants, applicants must be current grantees of LSC Basic Field-General, Basic Field-Migrant, or Basic Field-Native American grants. In addition, applicants must receive basic field funding of at least a one-year term, be up to date on reporting on any existing TIG-funded projects, and not have had a previous TIG terminated in the past three years for reporting or other performance issues.

B. Technology Initiative Grant Purpose and Key Goals

Since LSC's TIG program was established in 2000, LSC has made over 826 grants totaling over $77 million. This grant program encourages organizations to use technology in innovative ways to:

1. Effectively and efficiently provide high-quality legal assistance to low-income persons and to promote access to the judicial system through legal information, advice, and representation.

2. Improve service delivery, quality of legal work, and management and administration of grantees.

3. Develop, test, and replicate innovative strategies that can enable grantees and state justice communities to improve clients' access to high-quality legal assistance.

C. Funding Categories

1. General Technology Initiative Grants

Projects in this category (1) implement new or innovative approaches for using technology in legal services delivery; (2) enhance the effectiveness and efficiency of existing technologies so that they may be better used to increase the quality and quantity of services to clients; or (3) replicate, adapt, or provide added value to the work of prior technology projects. This includes, but is not limited to, the implementation and improvement of tested methodologies and technologies from previous TIG projects. We also encourage replication of proven technologies from non-LSC funded legal aid organizations as well as sectors outside the legal aid community.

LSC recommends a minimum amount for funding requests in this category of $40,000, but projects with lower budgets will be considered. There is no maximum amount for TIG funding requests that are within the total appropriation for TIG. All applicants in this category must submit a pre-application according to the process and requirements outlined in this notice.

2. Technology Improvement Projects

LSC recognizes that grantees need sufficient technology infrastructure in place before they can take on a more innovative TIG project, and this grant category is for applicants that need to improve their basic technology infrastructure or their information security posture. The maximum funding amount for this category is $35,000.

Please note that Technology Improvement Projects do not require a pre-application. LSC will open the application system and provide guidance for this project category by April 15, 2022. The application deadline for Technology Improvement Projects is May 20, 2022.

D. Available Funds for 2022 Grants

The availability of funds for Technology Initiative Grants for FY2022 depends on LSC's appropriation. LSC is currently operating under a Continuing Resolution for FY2022, which funds the federal government through February

18, 2022. The Continuing Resolution maintains funding at $4,250,000. Technology Initiative Grant decisions for FY2022 will be made by September 2022. LSC anticipates publicizing the total amount available for Technology Initiative Grants when Congress enacts the FY2022 appropriation.

LSC will not designate fixed or estimated amounts for the two different funding categories and will make grant awards for the two categories within the total amount of funding available.

E. Grant Terms

Applicants to the Technology Initiative Grant (TIG) program may propose grant terms between 12 and 36 months for general category projects and between 12 and 18 months for technology improvement projects. The grant term is expected to commence on October 1, 2022.

III. Grant Application Process

A. Technology Initiative Grant Application Process

The Technology Initiative Grant (TIG) application process will be administered in LSC's unified grants management system, GrantEase. Applicants must first submit a pre-application to LSC in GrantEase by March 18, 2022, at 11:59 p.m. EDT, to be considered for a grant. After review by LSC staff, LSC's president decides which applicants will be asked to submit a full application. Applicants will be notified of approval to submit a full application by late-April 2022. Full applications are due to LSC in the GrantEase system on June 3, 2022, at 11:59 p.m. EDT. Once received, full applications will undergo a rigorous review by LSC staff. LSC's president makes the final decisions on funding for the Technology Initiative Grant program.

As noted above, applicants applying for Technology Improvement Project funding are not requirered to submit pre-applications. LSC will launch the online application system for these projects by April 15, 2022, and set a submission deadline of May 20, 2022, at 11:59 p.m. EDT.

B. Late or Incomplete Applications

LSC may consider a request to submit a pre-application after the deadline, but only if the applicant has submitted an email to *techgrants@lsc.gov* explaining the circumstances that caused the delay prior to the pre-application deadline. Communication with LSC staff, including assigned program liaisons, is not a substitute for sending a formal request and explanation to *techgrants@lsc.gov.* At its discretion, LSC may consider incomplete applications. LSC will determine the admissibility of late or incomplete applications on a case-by-case basis.

C. Multiple Pre-Applications

Applicants may submit multiple pre-applications under the same or different funding category. If applying for multiple grants, applicants should submit separate pre-applications for each funding request.

D. Additional Information and Guidelines

Additional guidance and instructions on the pre-application and application processes for Technology Initiative Grants will be available and regularly updated at *https://www.lsc.gov/grants/technology-initiative-grant-program.*

Authority: 42 U.S.C. 2996g(e).

Dated: February 1, 2022.

Stefanie Davis,

Senior Associate General Counsel for Regulations.

[FR Doc. 2022–02376 Filed 2–3–22; 8:45 am]

BILLING CODE 7050–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0188]

Information Collection: Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274.''

DATES: Submit comments by April 5, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0188. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the ''For Further Information Contact'' section of this document.

• *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0188 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2021–0188. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2021–0188 on this website.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML21321A235.

• *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. (ET), Monday through Friday, except Federal holidays.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0188 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov/* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Part 150 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274.''

2. *OMB approval number:* 3150–0032.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* One-time or as needed.

6. *Who will be required or asked to respond:* Agreement States who have signed Section 274(b) Agreements with the NRC.

7. *The estimated number of annual responses:* 8.

8. *The estimated number of annual respondents:* 8.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 190.

10. *Abstract:* The NRC regulations in 10 CFR part 150, provide certain exemptions to persons in Agreement States from the licensing requirements contained in Chapters 6, 7, and 8 of the Atomic Energy Act of 1954, as amended, and certain regulations of the Commission. The regulations in 10 CFR part 150 also define the Commission's continued regulatory authority over Agreement State activities which include byproduct, source, and special nuclear material reporting requirements related to reciprocity and enforcement. 10 CFR part 150 requires telephonic notification to the NRC when an Agreement State licensee identifies attempted theft or diversion of special nuclear material, byproduct material, and tritium. This notification must be followed by a written report either 15 or 60 days after the initial report, depending on the materials involved. If additional information is available after submission of the written report, an additional report is submitted. These reports are used to inform the Commission, staff, and other Federal agencies when special nuclear material, byproduct material, or tritium is lost or stolen.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the estimate of the burden of the information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: February 1, 2022.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2022–02370 Filed 2–3–22; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information (RFI) on Strengthening Community Health Through Technology; Correction

AGENCY: White House Office of Science and Technology Policy (OSTP).

ACTION: Notice; correction.

SUMMARY: OSTP published a document in the **Federal Register** of January 5, 2022, requesting input on how digital health technologies are used, or could be used in the future, to transform community health, individual wellness, and health equity. The document closing date was stated as February 28, 2022. We are extending the closing date to March 31, 2022 to allow more time for input.

FOR FURTHER INFORMATION CONTACT: Jacqueline Ward at *connectedhealth@ostp.eop.gov* or by voicemail at 202–456–3030.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of January 5, 2022, in FR Doc. 2021–28193, on page 492, in the second column, correct the **DATES** caption to read:

DATES: Interested persons and organizations are invited to submit comments on or before 5:00 p.m. ET on March 31, 2022.

Dated: January 31, 2022.

Stacy Murphy,

Operations Manager.

[FR Doc. 2022–02289 Filed 2–3–22; 8:45 am]

BILLING CODE 3270–F1–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94101; File No. SR–ICEEU–2022–001]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the Clearing Fees for ICE Futures Europe FTSE 100 Index Futures and Options, FTSE 100 Dividend Index Futures and the Clearing Fee Caps for FTSE 100 Index Options

January 31, 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 January 19, 2022, ICE Clear Europe Limited

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared primarily by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] such that the proposed rule change was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed amendments is for ICE Clear Europe to amend the clearing fees for ICE Futures Europe FTSE 100 Index Futures and Options, FTSE 100 Dividend Index Futures and the clearing fee caps for FTSE 100 Index Options. The proposed amendments do not involve any changes to the ICE Clear Europe Clearing Rules or Procedures.[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

The purpose of the proposed rule changes is for ICE Clear Europe to amend the clearing fees for FTSE 100 Index Futures and Options and the FTSE 100 Dividend Index Futures (the ''Contracts'') and to amend the clearing fee caps that are currently applied to FTSE 100 Index Options block trades.

Following review, and in consultation with ICE Futures Europe (the exchange on which the Contracts are traded), ICE Clear Europe proposes to increase the clearing fees for the FTSE 100 Index derivatives to support the additional development of the Contracts, noting that the last time the fees were reviewed was in January 2019 for the FTSE 100 Index Futures and the FTSE 100 Dividend Index Futures, and in October 2019 for the FTSE 100 Index Options. The decision to amend fees has been made in conjunction with ICE Futures Europe, and accordingly the fee tables below and in Exhibit 5 also include for information purposes the proposed exchange fee changes. The proposed new fees are intended to come into effect on 1 February 2022, subject to regulatory approval, and ICE Clear Europe intends to publish a Circular to inform market participants of the changes to the fee schedule in advance of such proposed effective date. The proposed revisions to the fees are described in further detail below.

FTSE 100 Futures and Options Proposed Transaction Fees

The Clearing House is proposing the increases noted below to the FTSE 100 Index Futures and Option clearing transaction fees associated with Screen, Block/Basis and Block with Delayed Publication. In addition, the Clearing House proposes to increase the fee caps that are currently applied to FTSE 100 Index Options block trades. Below is a table showing the current clearing fees and a table showing the proposed amended clearing fees.

Contract Levies for FTSE 100 Index Futures and Options:

Current Fees:

Contract levies	Fee (£)		
	Exchange	Clearing	Total
Outrights/Basis	0.09	0.21	0.30
Block	0.04	0.26	0.30
Block with Delayed Publication	0.05	0.30	0.35
Cash Settlement fee (Futures) [6]	0.00	0.30	0.30
Exercise/Assignment fee (Options)	0.00	0.30	0.30
Block fee cap (Options)	220	1,980	2,200
Block fee cap with Delayed Publication (Options)	300	2,700	3,000
Exercise/Assignment fee cap (Options)	0.00	2,200	2,200

Proposed Fees:

Contract levies	Fee (£)		
	Exchange	Clearing	Total
Outrights/Basis	0.11	0.24	0.35
Block	0.06	0.29	0.35
Block with Delayed Publication	0.07	0.33	0.40
Cash Settlement fee (Futures) [7]	0.00	0.35	0.35
Exercise/Assignment fee (Options)	0.00	0.35	0.35
Block fee cap (Options)	320	2,080	2,400
Block fee cap with Delayed Publication (Options)	400	2,800	3,200
Exercise/Assignment fee cap (Options)	0.00	2,400	2,400

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

[5] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules.

[6] Including FTSE 100 Index Futures Trade at Index Close (FTSE TIC).

[7] Including FTSE 100 Index Futures Trade at Index Close (FTSE TIC).

FTSE 100 Dividend Futures Proposed Transaction Fees

The Clearing House is proposing the increases noted below to the FTSE 100 Dividend Futures clearing transaction fees associated with Screen, Block/Basis and Block with Delayed Publication and with cash settlement. Below is a table showing the current clearing fees and a table showing the proposed amended clearing fees.

Contract Levies for FTSE 100 Dividend Index Futures:

Current Fees:

Contract levies	Fee (£)		
	Exchange	Clearing	Total
Outrights/Basis	0.09	0.21	0.30
Block	0.04	0.26	0.30
Block with Delayed Publication	0.05	0.35	0.40
Cash Settlement fee	0.00	0.30	0.30

Proposed Fees:

Contract levies	Fee (£)		
	Exchange	Clearing	Total
Outrights/Basis	0.11	0.24	0.35
Block	0.06	0.29	0.35
Block with Delayed Publication	0.07	0.33	0.40
Cash Settlement fee	0.00	0.35	0.35

(b) Statutory Basis

ICE Clear Europe believes that the proposed rule changes are consistent with the requirements of the Act, including Section 17A of the Act[8] and regulations thereunder applicable to it. In particular, Section 17A(b)(3)(D) of the Act[9] requires that ''[t]he rules of the clearing agency provide for the equitable allocation of reasonable dues, fees and other charges among its participants''. ICE Clear Europe believes that its clearing fees, as proposed to be amended, would be reasonable and appropriate for the relevant Contracts. ICE Clear Europe's fees are imposed at the product level on a per transaction basis (as are the applicable Exchange fees). As a result, the fees, as proposed to be modified, would apply to all market participants who trade and clear the Contracts. ICE Clear Europe has determined that the increased fees would be commensurate with the size of the contract and would provide an appropriate balance between the costs of clearing for market participants and the expenses incurred by ICE Clear Europe in offering clearing of the relevant contracts, taking into account the investments ICE Clear Europe has made in clearing such products. Exhibit 3 includes a quantitative analysis of the impact of the proposed fee changes. As such, in ICE Clear Europe's view, the amendments are consistent with the equitable allocation of reasonable dues, fees and other charges among its Clearing Members and other market participants, within the meaning of Section 17A(b)(3)(D) of the Act.[10]

The proposed amendments are also consistent with the requirements of Section 17A(b)(3)(F) of the Act[11] which requires, among other things, that ''[t]he rules of a clearing agency [. . .] are not designed to permit unfair discrimination in the admission of participants or among participants in the use of the clearing agency''. As noted above, the fees, as proposed to be amended, would apply on a per transaction and would apply to all Clearing Members. As a result, the amendments would not result in any unfair discrimination among Clearing Members in their use of the Clearing House, within the meaning of Section 17A(b)(3)(F) of the Act.[12]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. Although ICE Clear Europe is increasing certain clearing fees, as set forth herein, it believes such changes are appropriate to reflect the costs and expenses incurred by the Clearing House in clearing the relevant Contracts. Further, as discussed above, because fees are imposed on a per transaction basis at the product level, the changes to the fees are applied equally to all Clearing Members who trade and/or clear the Contracts. ICE Clear Europe does not believe that the amendments would adversely affect the ability of such Clearing Members or other market participants generally to access clearing services for the Contracts. Further, since the revised fees will apply to all Clearing Members that clear the products, ICE Clear Europe believes that the amendments would not otherwise affect competition among Clearing Members, adversely affect the market for clearing services or limit market participants' choices for obtaining clearing services. As a result, ICE Clear Europe does not believe the amendments would have any impact or impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any comments received with respect to the proposed rule change.

[8] 15 U.S.C. 78q–1.

[9] 15 U.S.C. 78q–1(b)(3)(D).

[10] 15 U.S.C. 78q–1(b)(3)(D).

[11] 15 U.S.C. 78q–1(b)(3)(F).

[12] 15 U.S.C. 78q–1(b)(3)(F).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [13] and paragraph (f)(2) of Rule 19b–4 [14] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2022–001 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–ICEEU–2022–001. 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, security-based swap submission or advance notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.*

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–ICEEU–2022–001 and should be submitted on or before February 25, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–02313 Filed 2–3–22; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94096; File No. SR–Phlx–2022–04]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Proposed Rule Change To Update the Obvious Error Rule

January 31, 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 January 26, 2022, Nasdaq PHLX LLC (''Phlx'' 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 Options 3, Section 20 (Nullification and Adjustment of Options Transactions including Obvious Errors).

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/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

The purpose of this proposed rule change is to amend Options 3, Section 20 (Nullification and Adjustment of Options Transactions including Obvious Errors) to improve the operation of the Rule. Following discussions with other exchanges and a cross-section of industry participants and in coordination with the Listed Options Market Structure Working Group (''LOMSWG'') (collectively, the ''Industry Working Group''), the Exchange proposes: (1) To amend section (b)(3) of the Rule to permit the Exchange to determine the Theoretical Price of a Customer option transaction in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or re-opening; and (2) to amend section (c)(4)(B) of the Rule to adjust, rather than nullify, Customer transactions in Obvious Error situations, provided the adjustment does not violate the limit price. The foregoing changes are based on the recently amended rules of NYSE Arca, Inc. (''Arca'').[3] The Exchange further proposes to make a non-substantive, corrective change. Each change is discussed in detail below.

Proposed Change to Section (b)(3)

Options 3, Section 20 has been part of various harmonization efforts by the Industry Working Group.[4] These efforts

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Arca Rule 6.87–O. *See also* Securities Exchange Act Release No. 93818 (December 17, 2021), 86 FR 73009 (December 23, 2021) (SR–NYSEArca–2021–91) (Order Approving a Proposed Rule Change to Amend Rule 6.87–O).

[4] *See, e.g.,* Securities Exchange Act Release Nos. 74919 (May 8, 2015), 80 FR 27766 (May 14, 2015)

Continued

have often centered around the Theoretical Price for which an options transaction should be compared to determine whether an Obvious Error has occurred. For instance, all options exchanges have adopted language comparable to Supplementary Material .05,[5] which explains how an exchange is to determine Theoretical Price at the open, when there are no valid quotes, and when there is a wide quote. This includes at times the use of a singular third-party vendor, known as a TP Provider (currently CBOE Livevol, LLC).

Similarly, section (b)(3) of Options 3, Section 20 was previously harmonized across all options exchanges to handle situations where executions occur in markets that are wide (as set forth in the rule).[6] Under that section, the Exchange determines the Theoretical Price if the NBBO for the subject series is wide immediately before execution and a narrow market (as set forth in the rule) existed ''during the 10 seconds prior to the transaction.'' The rule goes on to clarify that, should there be no narrow quotes ''during the 10 seconds prior to the transaction,'' the Theoretical Price for the affected series is the NBBO that existed at the time of execution (regardless of its width).

In recent discussions, the Industry Working Group has identified proposed changes to section (b)(3) of Options 3, Section 20 that would improve the Rule's functioning. Currently, section (b)(3) does not permit the Exchange to determine the Theoretical Price unless there is a narrow quote 10 seconds prior to the transaction. However, in the first seconds of trading, there is no 10-second period ''prior to the transaction.'' Further, the Industry Working Group has observed that prices in certain series can be disjointed at the start of trading. Accordingly, the Exchange proposes to provide additional protections to trading in certain circumstances immediately after the opening before liquidity has had a chance to enter the market. The Exchange proposes to amend section (b)(3) to allow the Exchange to determine the Theoretical Price in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or reopening.

Specifically, the Exchange proposes that the existing text of section (b)(3) would become sub-section (A). The Exchange proposes to add the following heading and text as sub-section (B):

(B) Customer Transactions Occurring Within 10 Seconds or Less After an Opening or Re-Opening:

(i) The Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer's erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph (A) above and there was a bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction.

(ii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction, then the Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer's erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph (A) above and there was a bid/ask differential less than the Minimum Amount anytime during the 10 seconds after an opening or re-opening.

(iii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds following an Opening or Re-Opening, then the Theoretical Price of an option series is the last NBB or NBO just prior to the Customer transaction in question, as set forth in paragraph (b) above.

(iv) Customer transactions occurring more than 10 seconds after an opening or re-opening are subject to paragraph (A) above.

The following examples illustrate the functioning of the proposed rule change. Consider that the NBBO of a series opens as $0.01 at $4.00. A marketable limit order to buy one contract arrives one second later and is executed at $4.00. In the third second of trading, the NBBO narrows from $0.01 at $4.00 to $2.00 at $2.10. While the execution occurred in a market with wide widths, there was no tight market within the 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review, in part due to the fact that there was only a single second of trading before the execution. Under the proposal, since a tight market existed at some point in the first 10 seconds of trading (*i.e.,* in the third second), the Exchange would be able to determine the Theoretical Price as provided in Supplementary Material .05.

As another example, the NBBO for a series opens as $0.01 at $4.00. In the seventh second of trading, a marketable limit order is received to buy one contract and is executed at $4.00. Five seconds later (*i.e.,* in the twelfth second of trading), the NBBO narrows from $0.01 at $4.00 to $2.00 at $2.10. While the execution occurred in a market with wide widths, there was no tight market within 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review. Under the proposal, since no tight market existed at any point during the first 10 seconds of trading (*i.e.,* the narrow market occurred in the twelfth second), the trade would not qualify for obvious error review.

The proposed rule change would also better harmonize section (b)(3) with section(b)(1) of the Rule. Under section (b)(1), the Exchange is permitted to determine the Theoretical Price for transactions occurring as part of the Opening Process (as defined in Options 3, Section 8) if there is no NBB or NBO for the affected series just prior to the erroneous transaction. However, under the current version of section (b)(3), a transaction during regular trading hours could occur in the same wide market but the Exchange would not be permitted to determine the Theoretical Price. Consider an example where one second after the Exchange opens a selected series, the NBBO is $1.00 at $5.00. At 9:30:03, a customer submits a marketable buy order to the Exchange and pays $5.00. At 9:30:03, a different exchange runs an opening auction that results in a customer paying $5.00 for the same selected series. At 9:30:06, the NBBO changes from $1.00 at $5.00 to $1.35 at $1.45. Under the current version of section (b)(3), the Exchange would not be able to determine the Theoretical Price for the trade occurring during regular trading hours. However, the trade on the other exchange could be submitted for review under (b)(1) and that exchange would be able to determine the Theoretical Price. If the proposed change to section (b)(3) were approved, both of the trades occurring at 9:30:03 (on the Exchange during regular trading and on another exchange via auction) would also be entitled to the same review regarding the same Theoretical Price based upon the same time.

The proposal would not change any obvious error review beyond the first 10 seconds of an opening or re-opening.

Proposed Change to Section (c)(4)(B)

The Exchange proposes to amend section (c)(4)(B)—the ''Adjust or Bust'' rule for Customer transactions in Obvious Error situations—to adjust rather than nullify such orders, provided the adjustment does not violate the Customer's limit price. Currently, the Rule provides that in Obvious Error situations, transactions involving non-Customers should be adjusted, while transactions involving Customers are nullified, unless a certain

(SRP–hlx–2015–43); 80431 (April 11, 2017), 82 FR 18182 (April 17, 2017) (SRP–hlx–2017–27).

[5] *See, e.g.,* Securities Exchange Act Release No. 81352 (August 8, 2017), 82 FR 37949 (August 14, 2017) (SRP–hlx–2017–66).

[6] *See, e.g.,* Securities Exchange Act Release Nos. 74919 (May 8, 2015), 80 FR 27766 (May 14, 2015) (SR–Phlx–2015–43).

condition applies.[7] The Industry Working Group has concluded that the treatment of these transactions should be harmonized under the Rule, such that transactions involving Customers may benefit from adjustment, just as non-Customer transactions currently do, except where such adjustment would violate the Customer's limit price; in that instance, the trade would be nullified.

Specifically, the Exchange proposes to amend the text of section (c)(4)(B) to add that where at least one party to the Obvious Error is a Customer, ''the execution price of the transaction will be adjusted by the Official pursuant to the table immediately above. Any Customer Obvious Error exceeding 50 contracts will be subject to the Size Adjustment Modifier defined in sub-paragraph (a)(4) above. However, if such adjustment(s) would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price,'' the trade will be nullified. The ''table immediately above'' referenced in the proposed text refers to the table at current Section (c)(4)(A), which provides for the adjustment of prices a specified amount away from the Theoretical Price, rather than adjusting the Theoretical Price.

Non-Substantive Amendment

The Exchange proposes a non-substantive change in Options 3, Section 20(j) to update the reference to the definition of Plan therein to Options 3, Section 1(n) to Options 5, Section 1(n).

Implementation Date

The proposed rule change will become operative no sooner than six months following the approval of the Arca proposal to coincide with implementation on other options exchanges.[8] The Exchange will announce the effective date of the proposed changes in an alert distributed to all Members.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change to section (b)(3) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because it provides a method for addressing Obvious Error Customer transactions that occur in a wide market at the opening of trading. Generally, a wide market is an indication of a lack of liquidity in the market such that the market is unreliable. Current section (b)(3) recognizes that a persistently wide quote (*i.e.,* more than 10 seconds) should be considered the reliable market regardless of its width, but does not address transactions that occur in a wide market in the first seconds of trading, where there is no preceding 10-second period to reference. Accordingly, in the first 10 seconds of trading, there is no opportunity for a wide quote to have persisted for a sufficiently lengthy period such that the market should consider it a reliable market for the purposes of determining an Obvious Error transaction.

The proposed change would rectify this disparity and permit the Exchange to consider whether a narrow quote is present at any time during the 10-second period after an opening or re-opening. The presence of such a narrow quote would indicate that the market has gained sufficient liquidity and that the previous wide market was unreliable, such that it would be appropriate for the Exchange to determine the Theoretical Price of an Obvious Error transaction. In this way, the proposed rule harmonizes the treatment of Customer transactions that execute in an unreliable market at any point of the trading day, by making them uniformly subject to Exchange determination of the Theoretical Price.

The Exchange believes that the proposed change to section (c)(4)(B) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by harmonizing the treatment of non-Customer transactions and Customer transactions under the Rule. Under the current Rule, Obvious Error situations involving non-Customer transactions are adjusted, while those involving Customer transactions are generally nullified, unless they meet the additional requirements of section (c)(4)(C) (*i.e.,* where a member or member organization has 200 or more Customer transactions under review concurrently and the orders resulting in such transactions were submitted during the course of 2 minutes or less). The proposal would harmonize the treatment of non-Customer and Customer transactions by providing for the adjustment of all such transactions, except where such adjustment would violate the Customer's limit price.

When it proposed the current rule in 2015, the Exchange believed there were sound reasons for treating non-Customer transactions and Customer transactions differently. At the time, the Exchange stated its belief that ''Customers are not necessarily immersed in the day-to-day trading of the markets, are less likely to be watching trading activity in a particular option throughout the day, and may have limited funds in their trading accounts,'' and that nullifying Obvious Error transactions involving Customers would give Customers ''greater protections'' than adjusting such transactions by eliminating the possibility that a Customer's order will be adjusted to a significantly different price. The Exchange also noted its belief that ''Customers are . . . less likely to have engaged in significant hedging or other trading activity based on earlier transactions, and thus, are less in need of maintaining a position at an adjusted price than non-Customers.[11]

Those assumptions about Customer trading and hedging activity no longer hold. The Exchange and the Industry Working Group believe that over the course of the last five years, Customers that use options have become more sophisticated, as retail broker-dealers have enhanced the trading tools available. Pursuant to OCC data, volumes clearing in the Customer range have expanded from 12,022,163 ADV in 2015 to 35,081,130 ADV in 2021. This increase in trading activity underscores the greater understanding of options by Customers as a trading tool and its use in the markets. Customers who trade options today largely are more educated, have better trading tools, and have better access to financial news than any

[7] Specifically, the current Rule provides at section (c)(4)(C) that if a member or member organization has 200 or more Customer transactions under review concurrently and the orders resulting in such transactions were submitted during the course of 2 minutes or less, where at least one party to the Obvious Error is a non-Customer, then the Exchange will apply the non-Customer adjustment criteria found in section (c)(4)(A).

[8] *See supra* note 3.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *See* Securities Exchange Act Release Nos. 74919 (May 8, 2015), 80 FR 27766 (May 14, 2015) (SR–Phlx–2015–43).

time prior.[12] The proposed rule would extend the hedging protections currently enjoyed by non-Customers to Customers, by allowing them to maintain an option position at an adjusted price, which would in turn prevent a cascading effect by maintaining the hedge relationship between the option transaction and any other transactions in a related security.

The Exchange believes that extending such hedging protections to Customer transactions would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by providing greater certainty of execution for all participants to options transactions. Under the current Rule, a Customer that believes its transaction was executed pursuant to an Obvious Error may be disincentivized from submitting the transaction for review, since during the review process, the Customer would be uncertain whether the trade would be nullified, and if so, whether market conditions would still permit the opportunity to execute a related order at a better price after the nullification ruling is finalized. In contrast, under the proposed rule, the Customer would know that the only likely outcomes of submitting a trade to Obvious Error review would be that the trade would stand or be re-executed at a better price; the trade would only be nullified if the adjustment would violate the order's limit. Similarly, under the current Rule, during the review period, a market maker who traded contra to the Customer would be uncertain if it should retain any position executed to hedge the original trade, or attempt to unwind it, possibly at a significant loss. Under the proposed rule change, this uncertainty is largely eliminated, and the question would be whether the already-executed and hedged trade would be adjusted to a better price for the Customer, or if it would stand as originally executed. In this way, the proposed rule enhances the protection of investors and removes impediments to and perfects the mechanism of a free and open market and a national market system.

The proposed rule also addresses the concern the Exchange cited in its 2015 filing that adjusting, rather than nullifying, Customer transactions could lead to a Customer's order being adjusted to a significantly different price. To address that concern, the proposed rule would prevent Customer transactions from being adjusted to a price that violates the order's limit; if the adjustment would violate a Customer's limit, the trade would instead be nullified. The Exchange believes it is in the best interest of investors to expand the availability of adjustments to Customer transactions in all Obvious Error situations except where the adjustment would violate the Customer's limit price.

Further, the Exchange believes that, with respect to such proposed adjustments to Customer transactions, it is appropriate to use the same form of adjustment as is currently in place with respect to non-Customer transactions as laid out in the table in section (c)(4)(A). That is, the Exchange believes that it is appropriate to adjust to prices a specified amount away from the Theoretical Price rather than to adjust the Theoretical Price, even though the Exchange has determined a given trade to be erroneous in nature, because the parties in question should have had some expectation of execution at the price or prices submitted. Also, it is common that by the time it is determined that an Obvious Error has occurred, additional hedging and trading activity has already occurred based on the executions that previously happened. The Exchange believes that providing an adjustment to the Theoretical Price in all cases would not appropriately incentivize market participants to maintain appropriate controls to avoid potential errors, while adjusting to prices a specified amount away from the Theoretical Price would incentivize such behavior.

The Exchange believes that the proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed change to section (b)(3) would apply to all instances of a wide market occurring within the first 10 seconds of trading followed by a narrow market at any point in the subsequent 10-second period, regardless of the types of market participants involved in such transactions. The proposed change to section (c)(4)(B) would harmonize the treatment of Obvious Error transactions involving Customers and non-Customers, no matter what type of market participants those parties may be.

Lastly, the Exchange believes that the non-substantive correction to update the rule cite within Options 3, Section 20(j) is consistent with the Act because it will bring greater transparency to the Rulebook and reduce potential confusion by investors.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange 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 anticipates that the other options exchanges will adopt substantively similar proposals, such that there would be no burden on intermarket competition from the Exchange's proposal. Accordingly, the proposed change is not meant to affect competition among the options exchanges. For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[12] *See* ''Retail Traders Adopt Options En Masse'' by Dan Raju, available at *https://www.nasdaq.com/articles/retail-traders-adopt-options-en-masse-2020-12-08.*

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

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–Phlx–2022–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2022–04. 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–Phlx–2022–04 and should be submitted on or before February 25, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–02312 Filed 2–3–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94109; File No. SR–NYSECHX–2022–01]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Rules To Remove Obsolete References

January 31, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on January 27, 2022, the NYSE Chicago, Inc. (''NYSE Chicago'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules to remove obsolete references to the Board of Governors and constitution of the Exchange. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules to remove obsolete references to the Board of Governors and constitution of the Exchange. In 2005 the Exchange's ownership structure was demutualized.[4] As part of that change, a Board of Directors replaced the Board of Governors as the governing body of the Exchange.[5] The Exchange filed an updated certificate of incorporation and bylaws and ceased having a constitution.[6]

Although most references in the Exchange rules to the Board of Governors and constitution were removed or updated at the time of the demutualization, some obsolete references remain.[7] To update those obsolete references, the Exchange proposes to make the following non-substantive changes.

- References to the ''Board of Governors'' would be revised to refer to the ''Board of Directors'' instead. Accordingly, the Exchange proposes to

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 51149 (February 8, 2005), 70 FR 7531 (February 14, 2005) (SR–CHX–2004–26) (Order Approving Proposed Rule Change and Amendment No. 1 and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 3 by the Chicago Stock Exchange, Inc. Relating to the Demutualization of the Chicago Stock Exchange, Inc.).

[5] *See* Section Fifth of Exhibit A to Amendment 1, SR–CHX–2004–26 (November 24, 2004), available at *https://www.sec.gov/rules/sro/chx/34-50892exa.pdf* (stating that ''[t]he governing body of the Corporation shall be its Board of Directors''). *See also* Securities Exchange Act Release No. 50892 (December 20, 2004), 69 FR 77796 (December 28, 2004) (SR–CHX–2004–26) (Notice of Filing of Amendment 1) and 70 FR 7531, *supra* note 4, at 7531 (''CHX will have its own Board of Directors that will manage CHX's business and affairs'') & 7534 (description of Board of Directors).

[6] *See* Exhibit A and Exhibit B to Amendment 1, SR–CHX–2004–26 (November 24, 2004), available at *https://www.sec.gov/rules/sro/chx/34-50892exa.pdf* and *https://www.sec.gov/rules/sro/chx/34-50892exb.pdf* (removing all references to the ''Constitution'' by either replacing them with references to the ''bylaws'' or deleting them). *See also* 69 FR 77796, *supra* note 5. The current governing documents of the Exchange are the Second Amended and Restated Certification of Incorporation of NYSE Chicago, Inc., available at *https://www.nyse.com/publicdocs/nyse/regulation/nyse/NYSE_Chicago_Second_Amended_and_Restated_Certificate_of_Incorporation.pdf, and Second Amended and Restated By-laws of NYSE Chicago, Inc.,* available at *https://www.nyse.com/publicdocs/nyse/regulation/nyse/NYSE_Chicago_Second_Amended_and_Restated_Bylaws.pdf.*

[7] *See* Exhibit E to Amendment 1, SR–CHX–2004–26 (November 24, 2004), available at *https://www.sec.gov/rules/sro/chx/34-50892exe.pdf. See also* 69 FR 77796, *supra* note 5.

replace ''Governors'' with ''Directors'' in Article 13, Rule 4(d) (Procedure for Reinstatement), and Article 22, Rule 2 (Admittance to Listing), Rule 3 (Suspension of Securities), Rule 5 (Unlisted Trading Privileges), Rule 21 (Corporate Governance, Disclosure, and Miscellaneous Requirements), Rule 25 (Portfolio Depositary Receipts), and Rule 27 (Trust Issued Receipts).

- The text ''and Article VII of the Exchange Constitution'' would be deleted from Article 12, Rule 8 (Minor Rule Variations). Because there is no reference to ''disciplinary proceeding'' in the Second Amended and Restated By-laws of NYSE Chicago, Inc. (''By-laws''), the Exchange would not replace the reference with one to the Bylaws.
- In Article 22, Rule 25(b) and Rule 27(e), ''Constitution'' would be replaced with ''bylaws''.
- In Article 22, Rule 25(g), the text ''in the Exchange's Constitution or'' would be deleted. Because there is no limitation of liability in the Bylaws, the Exchange would not replace the reference with one to the Bylaws.

Finally, the Exchange proposes to amend Article 22, Rule 5, to (a) delete the redundant text ''by the Exchange'' and (b) add ''or her'' after ''his.'' Neither change is substantive.

The proposed rule change is a non-substantive change that does not impact the governance of the Exchange. The proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act[8] in general, and with Section 6(b)(5) of the Exchange Act[9] in particular, because it is designed to designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

In particular, the Exchange believes that the proposed non-substantive changes updating obsolete references would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed non-substantive changes would add clarity, transparency and consistency to the Exchange's rules. It would do so by removing obsolete references to the Board of Governors and constitution and either updating them with references to the Board of Directors and By-laws, respectively, or, in the case of the constitution, deleting the reference. In addition, with respect to Article 22, Rule 5, it would do so by making a non-substantive deletion of redundant text and revising ''his'' to read ''his or her.''

By making the changes, the Exchange would ensure that its rules are consistent with the existing corporate structure and governing documents, including the By-laws. The Exchange believes that market participants would benefit from the increased clarity, thereby reducing potential confusion and ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the Exchange's rules.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[10] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is ministerial in nature and is not designed to have any competitive impact. The proposed rule change is not intended to address competitive issues but is rather concerned with making non-substantive changes to update obsolete references in the Exchange rules. Since the proposal does not substantively modify system functionality or processes on the Exchange or put any market participants at a relative disadvantage compared to other market participants, the proposed changes will not impose any burden on competition.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[13] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSECHX–2022–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSECHX–2022–01. 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

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78f(b)(8).

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(2)(B).

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–NYSECHX–2022–01 and should be submitted on or before February 25, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–02315 Filed 2–3–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34491; 812–15276]

John Hancock Asset-Based Lending Fund and John Hancock Investment Management LLC

January 31, 2022.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed end investment companies to issue multiple classes of shares of beneficial interest with varying sales loads and to impose asset-based distribution and/or service fees.

APPLICANTS: John Hancock Asset-Based Lending Fund (the ''Trust''), and John Hancock Investment Management LLC (the ''Advisor'').

FILING DATES: The application was filed on October 21, 2021, and amended on November 5, 2021, and January 10, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below.

Hearing requests should be received by the Commission by 5:30 p.m. on February 25, 2022, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: *mark.goshko@klgates.com* and *pablo.man@klgates.com.*

FOR FURTHER INFORMATION CONTACT: Lisa Reid Ragen, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and condition, please refer to Applicants' application, dated January 10, 2022, which may be obtained via the Commission's website by searching for the file number, using the Company name box, at *http://www.sec.gov/search/search.htm,* or by calling (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–02325 Filed 2–3–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94104; File No. SR–NYSEAMER–2022–09]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend the NYSE American Options Fee Schedule

January 31, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on January 21, 2022, NYSE American LLC (''NYSE American'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE American Options Fee Schedule (''Fee Schedule'') regarding incentives relating to Complex Customer Best Execution Auctions. The Exchange proposes to implement the fee change effective January 21, 2022.[4] The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange originally filed to amend the Fee Schedule on December 29, 2021 (SR–NYSEAmer–2021–53), with an effective date of January 3, 2022, then withdrew such filing on January 12, 2022 (SR–NYSEAmer–2022–05), which latter filing the Exchange withdrew on January 21, 2022.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to modify the Fee Schedule regarding the qualifications for (1) the Alternative Initiating Participant Rebate, as set forth in Section I.G. (the ''Rebate''), and (2) the credit on Customer Electronic Simple and Complex executions set forth in Section I.H (the ''Credit'').

As further discussed below, the proposed changes are designed to encourage ATP Holders to initiate Complex Customer Best Execution (''CUBE'') Auctions while also maintaining levels of both Customer and Professional Electronic volume.[5]

The Exchange proposes to implement this fee change on January 21, 2022.

Proposed Rule Change

Alternative Initiating Participant Rebate

Section I.G. of the Fee Schedule sets forth the per contract fees and credits for executions associated with Single-Leg and Complex CUBE Auctions. To encourage participation in Complex CUBE Auctions, the Exchange offers rebates on certain initiating Complex CUBE volume. Currently, the Exchange offers the ACE Initiating Participant Rebate to ATP Holders that also qualify for the American Customer Engagement (''ACE'') Program[6] and an Alternative Initiating Participant Rebate (the ''Rebate'') for ATP Holders that do not qualify for the ACE program.[7] Both the ACE Initiating Participant Rebate and the Rebate for Complex CUBE orders provide for a rebate of $0.10 per contract, and an ATP Holder that qualifies for both rebates is entitled to only the greater of the two.[8]

Currently, to qualify for the Rebate, an ATP Holder must execute a minimum of 5,000 contracts ADV in the Professional range (as defined in Section I.H. of the Fee Schedule) and execute a minimum of 15,000 contracts ADV from Initiating CUBE Orders in Single-Leg and/or Complex CUBE Auctions.[9]

The Exchange proposes to modify the qualifications to earn the Rebate by decreasing the required volume in Initiating CUBE Orders from 15,000 ADV from Initiating CUBE Orders in Single-Leg and/or Complex CUBE Auctions to 10,000 ADV in Initiating CUBE orders from Complex CUBE Auctions only. The Exchange proposes to modify this qualification to be based only on Initiating CUBE Orders in Complex CUBE Auctions in order to encourage increased participation in Complex CUBE Auctions. The Exchange also proposes to delete the requirement to execute a minimum of 5,000 contracts ADV in the Professional range and proposes two additional qualifications to earn the Rebate. The Exchange proposes these changes to align the requirements for this incentive with those for the Credit (as further discussed below). Specifically, the Exchange proposes to require, in addition to the volume requirement with respect to Initiating CUBE Orders in Complex CUBE Auctions, that an ATP Holder also achieve Customer Electronic executions of 0.05% of TCADV (excluding CUBE Auctions, QCC Transactions, and volume from orders routed to another exchange) and Professional (as defined in Section I.H. of the Fee Schedule) Electronic executions of 0.03% of TCADV (excluding CUBE Auctions, QCC Transactions, and volume from orders routed to another exchange). The Exchange proposes to exclude CUBE Auctions, QCC Transactions, and volume from orders routed to another exchange from the calculations of Customer Electronic and Professional Electronic volume, consistent with exclusions set forth elsewhere in the Fee Schedule.[10] The Exchange proposes to exclude volume from CUBE Auctions, QCC Transactions, and orders routed to another exchange because volume from such transactions would be subject to separate pricing.[11] The Exchange does not propose to modify the amount of the Rebate (which will remain at $0.10 per contract), and an ATP Holder that qualifies for both the ACE Initiating Participant Rebate and the Rebate will continue to be entitled only to the greater of the two rebates.

Credit on Customer Electronic Simple and Complex Executions

The Exchange also proposes to modify the qualifications to earn the Credit. Currently, the Credit provides that ATP Holders are eligible to receive a credit of $0.10 per contract on Customer Electronic Simple and Complex executions, excluding CUBE Auctions, QCC Transactions, and volume from orders routed to another exchange, by meeting each of the following monthly qualification levels: (a) 15,000 contracts ADV from Initiating CUBE Orders in Complex CUBE Auctions; (b) Customer Electronic executions of 0.05% of TCADV, excluding CUBE Auctions, QCC Transactions, and volume from orders routed to another exchange; and (c) Professional Electronic executions of 0.03% of TCADV.[12]

The Exchange proposes to decrease the required volume in Initiating Complex CUBE Orders from 15,000 to 10,000 ADV, which, as discussed above, would align the qualifying bases for the Credit with the proposed requirements for the Rebate. While the Exchange is not proposing any changes to the qualifying requirements with respect to Customer or Professional Electronic executions or to the amount of the Credit, which will remain $0.10 per contract, the Exchange proposes to modify the Fee Schedule to clarify the Professional Electronic volume requirement. Specifically, the Exchange proposes to specify that qualifying Professional Electronic volume, like Customer Electronic qualifying volume, excludes CUBE Auctions, QCC Transactions, and volume from orders routed to another exchange. The Exchange proposes this change to improve the clarity of the Fee Schedule by providing additional detail regarding how qualifying volume for the Credit is currently determined.

* * * * *

The proposed changes are designed to incent ATP Holders to direct order flow to the Exchange and to encourage ATP Holders to engage in a variety of transactions on the Exchange. In particular, the Exchange notes that volume executed in auctions has increased across the industry and thus believes the proposed change would

[5] For purposes of this filing, ''Professional'' Electronic volume includes: Professional Customer, Broker Dealer, Non-NYSE American Options Market Maker, and Firm.

[6] *See* Fee Schedule, Section I.E., American Customer Engagement (''ACE'') Program, *available at: https://www.nyse.com/publicdocs/nyse/markets/american-options/NYSE_American_Options_Fee_Schedule.pdf.*

[7] *See id.* at Section I.G., CUBE Auction Fees and Credits, Complex CUBE Auction.

[8] *See id.*

[9] *See id.*

[10] *See, e.g.,* Fee Schedule, Section I.C., NYSE American Options Market Maker Sliding Scale—Electronic (excluding volumes attributable to QCC trades and CUBE Auctions from calculation of Market Maker Electronic monthly volumes); Section I.E., American Customer Engagement (''ACE'') Program (excluding volume resulting from QCC trades and volume attributable to orders routed to another exchange from calculation of an OFP's Electronic volume); Section I.H., Professional Step-Up Incentive (excluding volumes from CUBE Auctions and QCC transactions from the calculation of base volume and qualifying volume for the incentive).

[11] *See* Fee Schedule, Sections I.F. (setting forth fees and credits for QCC trades) and I.G. (setting forth fees and credits for CUBE Auctions). Volume from orders routed to another exchange would be subject to pricing set forth by such exchange.

[12] *See* Fee Schedule, Section I.H. In calculating an OFP's Electronic volume, the Exchange will include the activity of either (i) Affiliates of the OFP, such as when an OFP has an Affiliated NYSE American Options Market Making firm, or (ii) an Appointed MM of such OFP.

encourage ATP Holders to direct more auction-eligible order flow (and, in particular, Initiating CUBE Orders in Complex CUBE auctions) to the Exchange to qualify for the Rebate and Credit.[13] To the extent that the proposed changes to the Rebate and Credit achieve their intended purpose, the increased liquidity on the Exchange would result in enhanced market quality for all participants.

The Exchange's fees are constrained by intermarket competition, as ATP Holders may direct their order flow to any of the 16 options exchanges, including one with an incentive program similar to the Rebate and Credit.[14] Thus, ATP Holders have a choice of where they direct their order flow. The proposed modifications to the qualifications for the Rebate and Credit are designed to encourage the submission of Complex CUBE Orders, which should maximize price improvement opportunities. In addition, because both the Rebate and Credit will also have requirements based on Customer Electronic executions and Professional Electronic order flow, as modified, the Exchange believes all market participants stand to benefit from increased order flow, which promotes market depth, facilitates tighter spreads, and enhances price discovery.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[15] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[16] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [17]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[18] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in November 2021, the Exchange had less than 8% market share of executed volume of multiply-listed equity and ETF options trades.[19]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, changes to exchange transaction fees and rebates can have a direct effect on the ability of an exchange to compete for order flow.

The proposed rule change is designed to continue to incent ATP Holders to direct liquidity to the Exchange in a variety of forms and from a variety of sources, thereby promoting market depth, price discovery, and price improvement and enhancing order execution opportunities for market participants. In particular, the Exchange believes it is reasonable to provide ATP Holders with a rebate or credit for achieving certain volume goals in different types of executions, consistent with credits offered through a similarly structured program on a competing options exchange.[20] The Exchange also believes that the proposed exclusions applicable to qualifying volume for the Rebate are reasonable because they are consistent with exclusions set forth elsewhere in the Fee Schedule, based on CUBE Auctions, QCC trades, and volume from orders routed to another exchange being subject to separate fees and credits.[21]

The Exchange also believes that the proposed modifications to the qualifications for the Rebate and the Credit are reasonably designed because they would encourage ATP Holders to execute a variety of orders on the Exchange and, in particular, make greater use of Complex CUBE Auctions. The Exchange further believes that implementing the same criteria to qualify for the Rebate or Credit should encourage greater use of the Exchange by all ATP Holders, which may lead to greater opportunities to trade—and for price improvement—for all participants. The Exchange notes that all market participants stand to benefit from increased transaction volume, as such increase promotes market depth, facilitates tighter spreads and enhances price discovery, and may lead to a corresponding increase in order flow from other market participants.

The Exchange believes that the proposed modification of the Fee Schedule regarding qualifying Professional Electronic volume for the Credit is reasonable because it will provide additional clarity regarding the current method of calculating qualifying volume for the Credit.

The Exchange cannot predict with certainty whether any ATP Holders would seek to qualify for the Rebate or the Credit, as modified, but believes that the proposed qualifying bases for the Rebate and Credit, which lower the volume of CUBE Orders necessary to qualify and align the volume requirements in Customer and Professional Electronic executions across the two incentives, are achievable for ATP Holders and would continue to incent ATP Holders to direct volume to the Exchange.

Finally, to the extent the proposed changes attract greater volume and liquidity, the Exchange believes the proposed changes would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule changes are a reasonable attempt by

[13] The Exchange's analysis of OPRA data indicates that auction volume has fluctuated from 19.2% of all options industry volume at the end of 2019, to as high as 23.4% in June 2020, to a current level of 19.7% in November 2021.

[14] *See, e.g.,* Cboe Exchange Inc. Fee Schedule, Volume Incentive Program, available at: *https://cdn.cboe.com/resources/membership/Cboe_FeeSchedule.pdf* (providing comparable per contract credits for Customer orders based on volume from a variety of executions, including auction volume, volume from various account types, and volume from both simple and complex executions).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(4) and (5).

[17] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[18] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

[19] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of ETF-based options, *see id.,* the Exchange's market share in multiply listed equity and ETF options decreased from 9.09% for the month of November 2020 to 7.06% for the month of November 2021.

[20] *See supra* note 14.

[21] *See supra* notes 10 & 11.

the Exchange to increase the depth of its market and improve its market share relative to its competitors.

The Proposed Rule Change Is an Equitable Allocation of Fees and Rebates

The Exchange believes the proposed rule change is an equitable allocation of its fees and rebates. The proposal is based on the amount and type of business transacted on the Exchange, and ATP Holders can seek to qualify for these incentives or not. The Exchange further believes that the proposed exclusion of CUBE Auctions, QCC trades, and volume routed to another exchange from the qualifying Customer Electronic and Professional Electronic volume for the Rebate is equitable because volume from such transactions is subject to separate pricing.[22] Moreover, because ATP Holders would need to meet requirements based on Initiating CUBE Orders, Customer Electronic executions, and Professional Electronic executions in order to qualify for either the Rebate or Credit, as modified, the Exchange believes that the proposed changes are designed to encourage ATP Holders to aggregate their executions at the Exchange as a primary execution venue. To the extent that the proposed changes attract more volume to the Exchange (and, in particular, more Complex CUBE auction volume), this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule changes would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery.

The Exchange also believes that the proposed change to specify that CUBE Auctions, QCC trades, and volume routed to another exchange are excluded from the calculation of qualifying Professional Electronic volume for the Credit is an equitable allocation of fees and rebates because the proposed exclusion is consistent with exclusions set forth elsewhere in the Fee Schedule and such transactions are subject to separate pricing.[23] The Exchange also believes that the proposed change promotes an equitable allocation of fees and rebates by ensuring that the Fee Schedule reflects the current method of calculating qualifying volume for the Credit.

The Proposed Rule Change Is not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory because the proposed modifications would apply to all similarly-situated market participants on an equal and non-discriminatory basis. The proposed changes are based on the amount and type of business transacted on the Exchange, and ATP Holders are not obligated to try to achieve either incentive. Rather, the proposals are designed to encourage participants to utilize the Exchange as a primary trading venue (if they have not done so previously) and increase auction, Customer Electronic, and Professional Electronic volume sent to the Exchange. In addition, the proposed modifications to the requirements to qualify for the Rebate and Credit are designed to align the requirements for the two incentives and to encourage greater use of Complex CUBE Auctions by ATP Holders, which may lead to greater opportunities to trade—and for price improvement—for all participants. The Exchange believes that the proposed exclusions from qualifying volume for the Rebate are not unfairly discriminatory because they are consistent with exclusions set forth elsewhere in the Fee Schedule and account for CUBE Auctions, QCC trades, and volume routed to another exchange being subject to separate pricing.[24]

To the extent that the proposed changes attract more executions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule changes would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange further believes that the proposed change to specify that CUBE Auctions, QCC trades, and volume routed to another exchange are excluded from the calculation of qualifying Professional Electronic volume for the Credit is not unfairly discriminatory because it would update the Fee Schedule to provide additional clarity regarding the current method of calculating qualifying volume for the Credit.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [25]

Intramarket Competition. The proposed change is designed to continue to attract increased and diverse order flow to the Exchange by offering competitive credits and rebates, which would enhance the quality of quoting and may increase the volume of contracts traded on the Exchange. Specifically, the Exchange believes the proposed rule change, by specifying requirements in auction, Customer Electronic, and Professional Electronic volume, would incent ATP Holders to participate in a variety of types of executions on the Exchange to qualify for the Rebate or Credit. To the extent that this purpose is achieved, all of the Exchange's market participants should benefit from the improved market liquidity. Enhanced market quality and increased transaction volume resulting from the anticipated increase in order flow directed to the Exchange would benefit all market participants and improve competition on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the

[22] *See supra* note 11.

[23] *See supra* notes 10 & 11.

[24] *See supra* notes 10 & 11.

[25] *See* Reg NMS Adopting Release, *supra* note 17, at 37499.

16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange currently has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[26] Therefore, no exchange currently possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in November 2021, the Exchange had less than 8% market share of executed volume of multiply-listed equity and ETF options trades.[27]

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees and rebates in a manner designed to encourage ATP Holders to direct trading interest to the Exchange, to provide liquidity and to attract order flow. Specifically, the Exchange believes that the proposed change would encourage ATP Holders to direct increased volume to the Exchange, thereby increasing the number of executions (and executions of varying types) on the Exchange. The Exchange further believes that harmonizing the requirements for the Rebate and Credit could make the incentives more achievable for ATP Holders and would thus continue to make the Exchange a more attractive and competitive venue for order execution. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

Thus, the Exchange believes that the proposed changes could promote competition between the Exchange and other execution venues, including those that currently offer similar pricing incentives, by encouraging additional orders to be sent to the Exchange for execution.

[26] *See supra* note 18.

[27] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of ETF-based options, *see id.,* the Exchange's market share in multiply listed equity and ETF options decreased from 9.09% for the month of November 2020 to 7.06% for the month of November 2021.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[28] of the Act and subparagraph (f)(2) of Rule 19b–4[29] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2022–09 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2022–09. 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–NYSEAMER–2022–09 and should be submitted on or before February 25, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–02314 Filed 2–3–22; 8:45 am]

BILLING CODE 8011–01–P

[28] 15 U.S.C. 78s(b)(3)(A).

[29] 17 CFR 240.19b–4(f)(2).

[30] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 11646]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: "Alberto Giacometti: Toward the Ultimate Figure" Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the exhibition ''Alberto Giacometti: Toward the Ultimate Figure'' at the Cleveland Museum of Art, Cleveland, Ohio; the Seattle Art Museum, Seattle, Washington; the Museum of Fine Arts, Houston, in Houston, Texas; the Nelson-Atkins Museum of Art, Kansas City, Missouri; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of

State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–02336 Filed 2–3–22; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36576]

Fortress Investment Group LLC—Exemption for Intra-Corporate Family Transaction—Ohio River Partners Shareholder LLC, Katahdin Railcar Services, LLC, Union Railroad Company, Gary Railway Company, Delray Connecting Railroad Company, Texas & Northern Railroad Company, and Lake Terminal Railroad Company

Fortress Investment Group LLC (Fortress), for the benefit of Fortress Transportation and Infrastructure Investors LLC (FTAI) and FTAI Infrastructure Inc. (FTAI Infrastructure),[1] (collectively, the Parties), has filed a verified notice of exemption for an intra-corporate family transaction under 49 CFR 1180.2(d)(3), which exempts from the prior approval requirements of 49 U.S.C. 11323 ''[t]ransactions within a corporate family that do not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with carriers outside the corporate family.'' 49 CFR 1180.2(d)(3).

According to the verified notice, FTAI indirectly owns controlling interests in seven common carrier railroads: Ohio River Partners Shareholder LLC (ORPS); Katahdin Railcar Services LLC (KRS); Union Railroad Company (URR); Gary Railway Company (GRW); Delray Connecting Railroad Company (DCR); Texas & Northern Railroad Company (TNR); and Lake Terminal Railroad Company (LTR).[2] The verified notice states that ORPS is a non-operating carrier,[3] and that the remaining railroads are each Class III carriers.[4] Under the proposed transaction, FTAI will engage in an intra-corporate reorganization that will result in FTAI Infrastructure's control of ORPS, KRS, URR, GRW, DCR, TNR, and LTR. The verified notice states that the purpose of the transaction is to separate FTAI's aviation-related assets and liabilities from its railroad and energy infrastructure businesses. According to the verified notice, an affiliate of Fortress will continue managing FTAI Infrastructure and, indirectly, the seven railroads. Fortress states that the proposed transaction does not impose or involve an interchange commitment by or affecting the railroads, and that it will have no impact on the day-to-day operations of the seven railroads.

Unless stayed, the exemption will be effective on February 20, 2022 (30 days after the verified notice was filed). Fortress states that the Parties intend to consummate the proposed transaction as soon as practicable after that date and final approval of the proposed transaction by FTAI's board of directors.[5]

The verified notice states that the transaction will not result in adverse changes in service levels, operational changes, or a change in the competitive balance with carriers outside the corporate family. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(3).

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. Accordingly, the Board may not impose labor protective conditions here because all the carriers involved are Class III rail carriers.

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 February 11, 2022 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36576, should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, one copy of each pleading must be served on Fortress's representative, Terence M. Hynes, Sidley Austin LLP, 1501 K Street NW, Washington, DC 20005.

According to Fortress, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and historic reporting under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: January 31, 2022.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Stefan Rice,

Clearance Clerk.

[FR Doc. 2022–02360 Filed 2–3–22; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36496]

Application of the National Railroad Passenger Corporation Under 49 U.S.C. 24308(e)—CSX Transportation, Inc., and Norfolk Southern Railway Company

AGENCY: Surface Transportation Board.

ACTION: Notice of public hearing.

SUMMARY: The Surface Transportation Board (Board) will hold a public hearing in this docket, consisting of two phases. The first phase, which will involve comments from the public, will commence on February 15, 2022, and

[1] The verified notice states that FTAI Infrastructure is a newly created subsidiary of FTAI, which is a Delaware limited liability company managed by an affiliate of Fortress.

[2] The verified notice states that FTAI owns 100% of the equity interests of Transtar, LLC, which owns and controls URR, GRW, DCR, TNR, and LTR. *See Fortress Inv. Grp. LLC—Acquis. & Continuance in Control Exemption—Ohio River Partners S'holder LLC,* FD 36521 (STB served June 30, 2021).

[3] The verified notice states that ORPS owns a 12.2-mile freight rail line between milepost 60.5 near Powhatan Point, Ohio, and milepost 72.2 near Hannibal, Ohio (the Omal Line). KRS has assumed the right and common carrier obligation to operate the Omal Line. *Katahdin Railcar Servs. LLC—Change in Operators Exemption—Ohio Terminal Ry.,* FD 36487 (STB served Mar. 30, 2021); *see also Fortress Inv. Grp. LLC—Exemption for Intra-Corp. Fam. Transaction—Ohio River Partners S'holder LLC,* FD 36402 (STB served May 15, 2020).

[4] According to the verified notice, the operating revenues of URR and GRW exceed the dollar threshold for Class II carrier status, but URR and GRW are designated as Class III carriers because they are switching and terminal carriers. *See* 49 CFR 1201.1–1(d).

[5] The verified notice states that the proposed transaction will be authorized by FTAI's board of directors pursuant to a written resolution in substantially the form attached to the verified notice as Exhibit 2.

will continue on February 16, 2022, if necessary. The second phase will be an evidentiary hearing commencing on March 9, 2022, and will be limited to the four parties to this case—the National Railroad Passenger Corporation (Amtrak), CSX Transportation, Inc. (CSXT), Norfolk Southern Railway Company (NSR), and the Alabama State Port Authority and its rail carrier division, the Terminal Railway Alabama State Docks (collectively, the Port; and with Amtrak, CSXT, and NSR, the ''Parties''). Immediately following the first phase, the Board will hold a conference with the Parties on February 16, 2022, to discuss issues related to the second phase.

DATES: The public hearing will commence on February 15, 2022, at 9:30 a.m., and will continue on February 16, 2022, if necessary. Notices of intent to participate shall be filed (and participants' email addresses separately provided to the Board via email) by February 7, 2022. The pre-evidentiary hearing conference with the Parties will be held on February 16, 2022, commencing at 9:30 a.m. or at the conclusion of the first phase of the hearing, whichever is later. At the conclusion of the pre-evidentiary hearing conference, the Board will recess the public hearing until March 9, 2022. Phase two, the evidentiary hearing on the record with the Parties, will be held beginning on March 9, 2022, at 9:30 a.m., and continuing on March 10, 2022, if necessary.

ADDRESSES: All filings, referring to Docket No. FD 36496, should be filed with the Surface Transportation Board via e-filing on the Board's website. Persons who file notices of intent to participate in the first phase of the public hearing shall concurrently provide to the Board, via email at *Hearings@stb.gov,* their email address.

FOR FURTHER INFORMATION CONTACT: Jonathon Binet at (202) 245–0368. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: On March 16, 2021, Amtrak filed an application with the Board, pursuant to 49 U.S.C. 24308(e), seeking an order requiring CSXT and NSR [1] to allow Amtrak to operate additional intercity passenger trains, consisting of two round-trips per day, over the rail lines of CSXT and NSR between New Orleans, La., and Mobile, Ala. The Board received numerous comments in response to Amtrak's application. By decision served August 6, 2021, the Board, among other things, denied CSXT and NSR's motion to dismiss the application, adopted a procedural schedule, and appointed Administrative Law Judge Thomas McCarthy to handle all discovery matters and resolve initially all discovery disputes.

In accordance with the procedural schedule, on November 3, 2021, CSXT and NSR filed opening evidence. On December 3, 2021, Amtrak filed reply evidence. On December 23, 2021, CSXT and NSR filed rebuttal evidence. The Board also received opening evidence, reply evidence, and rebuttal evidence from the Port, which the Board has permitted to intervene in this proceeding. On December 30, 2021, the Board received proposals on the format for the hearing from CSXT and NSR jointly and from Amtrak.

The initial phase of the hearing will commence on February 15, 2022. The primary purpose of this phase of the hearing is for interested persons, other than the four Parties to the case, to provide comments.[2] The hearing will continue on February 16, 2022, as necessary to accommodate participating persons. This initial phase of the hearing will be entirely virtual. It will be held online via Zoom and will be available for concurrent viewing on YouTube by the public. All interested persons are invited to appear at this phase of the public hearing. Any person wishing to participate in this phase of the public hearing shall file with the Board by February 7, 2022, a notice of intent to participate (identifying the entity, if any, the person represents; the proposed speaker; the amount of time requested; and briefly summarizing the key points that the speaker intends to address). The notices of intent to participate need not be served on any persons or entities; they will be posted to the Board's website when they are filed. Concurrently with filing a notice of intent to participate, persons wishing to participate in the public commentary phase of the hearing shall also provide to the Board, via email at *Hearings@stb.gov,* their email address.

The Board will issue, prior to commencement of the February 15 public hearing, a decision setting a schedule of appearances for speakers, with specific allotments of time for presentations. To ensure an opportunity for all interested persons to be heard, such allotments may be limited, and persons wishing to speak at the hearing should be prepared to keep their comments as succinct as possible, to ensure an opportunity for all interested persons to be heard. The Parties will be given an opportunity to respond after other interested persons have provided comments.

As noted, on February 16, 2022, beginning at 9:30 a.m. or immediately following the conclusion of the public commentary phase of the hearing, whichever is later, the Board will also hold a conference, at which counsel for the Parties are directed to appear. The conference will be entirely virtual. It will be held online via Zoom and will be available for concurrent viewing on YouTube by the public. During the conference, the Board and the Parties will discuss issues and procedures to be followed at the evidentiary hearing on the record. The Board encourages the Parties to meet and confer in advance of the conference, in an effort to narrow the issues to be heard at the hearing on the record and to stipulate to any facts that are not contested. Before the conference, the Board will issue a decision with additional information for the Parties, including what they will need to prepare in advance of the conference and further details on the evidentiary phase of the hearing, including whether it will be held online, in-person, or in a hybrid format. At the conclusion of the conference, the Board will recess the public hearing until commencement of the evidentiary phase at 9:30 a.m. on March 9, 2022.

On March 9, 2022, the Board will commence the evidentiary portion of the hearing, at which the Parties are directed to appear, and which will be open to the public. The evidentiary portion will involve participation by the Parties only and will be presided over by the entire Board. The Board will accept all of the previously filed evidence into the record. The evidentiary portion of the hearing is not intended as an opportunity for the Parties simply to restate the entirety of their written evidence or, on the other hand, to submit a substantially different case. Rather, the evidentiary portion of the hearing is intended to allow the Parties to illuminate their primary contentions, evidence, and points of disagreement through direct examination of witnesses, cross-examination, and re-direct examination, as appropriate, and through opening and closing presentations by counsel.

Board Releases and Transcript Availability: Decisions and notices of the Board, including this notice, are available on the Board's website at

[1] Although Amtrak names Norfolk Southern Corporation in its application, it appears that NSR is the proper party. (*See* Mot. to Dismiss 1 n.1.)

[2] The Board recognizes that this proceeding is an adjudication to be decided after a hearing on the record pursuant to 49 U.S.C. 24308(e), but given the broad public interest in Amtrak matters, the Board is also providing this opportunity for public comments.

www.stb.gov. A recording of the public commentary phase of the hearing, the conference, and the evidentiary phase of the hearing, as well as a transcript of each, will be posted on the Board's website when they become available.

It is ordered:

1. A public hearing in this proceeding will commence on February 15, 2022. All portions of the hearing taking place on February 15, 2022, and February 16, 2022, will be held online using video conferencing.

2. By February 7, 2022, any person who is not one of the Parties identified above and wishes to speak at the public portion of the hearing shall file with the Board a notice of intent to participate identifying the entity, if any, the person represents, the proposed speaker, and the amount of time requested, and also summarizing the key points that the speaker intends to address. Also by February 7, 2022, such persons shall submit, via email at *Hearings@stb.gov,* the email address of the speaker.

3. Notices of intent to participate will be posted to the Board's website and need not be served on any other persons or entities.

4. Counsel for Amtrak, CSXT, NSR, and the Port are directed to appear at a conference before the Board on February 16, 2022, at 9:30 a.m., or immediately following the conclusion of the public commentary phase of the hearing, whichever is later.

5. Amtrak, CSXT, NSR, and the Port are directed to appear at the evidentiary phase of the hearing before the Board beginning on March 9, 2022, at 9:30 a.m.

6. All evidence previously filed in this proceeding is accepted into the record.

7. This decision is effective on its service date.

8. This decision will be published in the **Federal Register**.

Decided: February 1, 2022.

By the Board, Board Members Fuchs, Hedlund, Oberman, Primus, and Schultz.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2022–02416 Filed 2–3–22; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2021–1086]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Aviation Maintenance Technician Schools; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice; correction.

SUMMARY: The FAA published a document in the **Federal Register** of November 23, 2021, concerning request for comments about the FAA's intention to request the Office of Management and Budget (OMB) approval to renew an information collection, in accordance with the Paperwork Reduction Act of 1995. The document was published with an incorrect docket number.

FOR FURTHER INFORMATION CONTACT: Tanya Glines by email at: *Tanya.glines@faa.gov;* phone: 202–380–5896.

SUPPLEMENTARY INFORMATION:

Correction: In the **Federal Register** of November 23, 2021, FR Doc. 2021–25472, on page 66615, in the third column, correct the docket number to read:

[Docket No. FAA–2021–1086]

Issued in Washington, DC, on February 1, 2022.

Tanya A. Glines,

Aviation Safety Inspector, FAA Safety Standards, Aircraft Maintenance Division.

[FR Doc. 2022–02356 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2018–0107 Notice 2]

Weldon, Denial of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition.

SUMMARY: Weldon, a Division of Akron Brass Company, has determined that certain backup lamps do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, Reflective Devices, and Associated Equipment.* Weldon filed a noncompliance report dated November 7, 2018, and subsequently petitioned NHTSA on November 30, 2018, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces the denial of Weldon's petition.

FOR FURTHER INFORMATION CONTACT: Leroy Angeles, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), (202) 366–5304, *Leroy.Angeles@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Overview

Weldon has determined that certain backup lamps it manufactures do not fully comply with paragraph S14.4.1 of FMVSS No. 108, *Lamps, Reflective Devices, and Associated Equipment* (49 CFR 571.108). Weldon filed a noncompliance report dated November 7, 2018, pursuant to 49 CFR part 556, *Defect and Noncompliance Responsibility and Reports,* and subsequently petitioned NHTSA on November 30, 2018, 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 Weldon's petition was published with a 30-day public comment period, on July 15, 2020, in the **Federal Register** (85 FR 42977). 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–2018–0107.''

II. Equipment Involved

Approximately 6,315 rear combination lamps manufactured between June 6, 2018, and June 25, 2018, are potentially involved.

III. Noncompliance

Weldon explains that its subject rear combination lamp is noncompliant because its backup lamp does not meet the requirements for color as specified in paragraph S14.4.1 of FMVSS No. 108. Specifically, the subject backup lamp, when tested in accordance with the Tristimulus Method, fell outside the required boundaries for white light.

IV. Rule Requirements

Paragraphs S14.4.1, S14.4.1.4.2, and S14.4.1.4.2.3, of FMVSS No. 108 includes the requirements relevant to this petition. The color of a sample device must comply when tested by

either the Visual Method or the Tristimulus Method. When tested using the Tristimulus method, the backup lamp color must comply with the color of light emitted within the following boundaries for white (achromatic):

- x = 0.31 (blue boundary)
- y = 0.44 (green boundary)
- x = 0.50 (yellow boundary)
- y = 0.15 + 0.64x (green boundary)
- y = 0.38 (red boundary)
- y = 0.05 + 0.75x (purple boundary)

V. Summary of Weldon's Petition

The following views and arguments presented in this section, ''V. Summary of Weldon's Petition,'' are the views and arguments provided by Weldon and do not reflect the views of the Agency. Weldon describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Weldon offers the following reasoning:

1. Weldon states that backup lamps are intended to signal to other drivers that a vehicle is in reverse gear. Weldon says that despite the slight deviation from the white color boundaries, the backup lamps, when engaged, are fully illuminated and are still sufficiently white in color that they will not create confusion (at any distance) that the truck is in the reverse gear. The lamps still comply with the luminous intensity photometry requirements of FMVSS No. 108. Weldon contends that even with the color specification noncompliance, these backup lamps fulfill the intended purpose of FMVSS No. 108 as it applies to signal lamps, namely to ensure signals are understood by other road users.

2. Weldon also argues that the vehicles for which the lamps have been supplied have full backup lamp functionality. This creates no safety risk, as the backup lamps are fully functional and remain completely illuminated. Further, Weldon states, the difference in color white light is very slight, so much so that the color is nearly imperceptible to the human eye at any distance. The lamps are sufficiently visible, effective, would not be confused with any other signal lamp, and do not create a safety risk.

3. In considering past petitions involving FMVSS No. 108, Weldon contends that NHTSA has previously considered and found deviations from the standard which were not perceptible to the human eye and/or did not affect the illumination or brightness of the lamp were inconsequential to motor vehicle safety. According to Weldon, NHTSA has found that deviation from the photometric parameters were inconsequential to safety when the overall intensity of the equipment was near to the required parameters to not be perceptible to the human eye. Weldon asserts that NHTSA has historically employed a rule that a margin of up to 25 percent deviation from FMVSS No. 108 photometric intensity requirements is reasonable to grant a petition of inconsequentiality for noncompliant signal lamps. *See* ''Driver Perception of Just Noticeable Differences of Automotive Signal Lamp Intensities,'' (herein, ''UMTRI Report'') DOT HS 808 209, Sept. 1994 (described by Weldon as a study sponsored by NHTSA that demonstrated that a change in luminous intensity of 25 percent or less is not noticeable by most drivers and is a reasonable criterion for determining the inconsequentiality of noncompliant signal lamps). According to Weldon, NHTSA has stated that it has granted such inconsequentiality petitions when it was ''confident that the noncompliant signal lights would still be visible to nearby drivers.'' [1] Moreover, Weldon notes that NHTSA has stated that ''because signal lighting is not intended to provide roadway illumination to the driver, a less than 25 percent reduction in light output at any particular test point is less critical.'' *Id.* Weldon points out that NHTSA has stated the UMTRI Report's findings to be ''mostly analogous to those of the signal lighting research.'' *Id.* Weldon also states that NHTSA granted a petition for a determination of inconsequentiality to General Motors for turn signals that met the photometry requirements in just three of four test groups and produced, on average, 90 percent of the required photometric intensity.[2] Weldon further states that NHTSA has granted similar petitions for lamps that do not comply with photometric requirements in other slight ways.

4. Conversely, Weldon states that NHTSA has denied inconsequentiality petitions in cases where headlamps do not meet the minimum FMVSS requirements, thus, causing an increased safety risk.[3] The purpose of headlamps, as opposed to rear signal lighting, is roadway illumination, which is crucial to road safety. Insufficient roadway illumination from nonconforming headlamps creates an increased safety risk to the public and thus is held to a higher standard than the 25 percent deviation of the UMTRI Report. *Id.* Backup indicator taillamps,[4] unlike headlamps, do not illuminate the road for drivers, and thus deviation from the FMVSS No. 108 color requirement of the standard does not impede visibility. Weldon says the backup lamps in question are still entirely visible (that is, the brightness of the tail lamps is not affected) [5] and still appear white to the human eye at any distance, as demonstrated by Weldon's findings. The lamps fulfill the intended purpose of FMVSS No. 108 as it applies to signal lamps, which is to make a driver's operating signals understood. Further, Weldon states that despite the slight deviation from the white light boundaries, the backup lamps would be understood to signal that the truck is in reverse gear and create no additional safety risk and fulfill the intent of FMVSS No. 108.

5. Weldon has not received any reports related to the performance of the lamps from the field and is not aware of any accidents or injuries related to the issue.

Weldon concludes 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.

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.[6] Potential performance failures of safety-critical equipment, are rarely deemed inconsequential.

An important issue to consider in determining inconsequentiality is the safety risk to individuals who

[1] *See General Motors Corporation; Denial of Application for Decision of Inconsequential Noncompliance,* 66 FR 38341 (July 23, 2001).

[2] *See General Motors Corporation; Grant of Application for Decision of Inconsequential Noncompliance,* 61 FR 1663 (January 22, 1996).

[3] *See General Motors Corporation; Denial of Application for Decision of Inconsequential Noncompliance,* 66 FR 38341 (July 23, 2001), for a denial of inconsequentiality petition where points on the headlamp used for overhead sign illumination were substantially below the photometric minimum values, which impaired driver visibility.

[4] NHTSA notes that Weldon uses the incorrect term ''backup indicator taillamps''. NHTSA believes that Weldon is referring to a ''backup lamp.''

[5] NHTSA believes that Weldon means that the backup lamp intensity is not affected.

[6] *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).

experience the type of event against which the recall would otherwise protect.[7] In general, NHTSA 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.'' [8] ''[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.'' [9]

One purpose of vehicle backup lamps is to indicate that a motor vehicle has engaged its reverse gear and is intending to move in that direction, which is a safety-critical alert to both pedestrians and drivers of other vehicles. Another purpose of the backup lamps is to serve as an illumination device so the driver can see what is behind the vehicle when moving in reverse.[10]

As an illumination device, the driver relies on the correct color of light for proper color rendering. Color rendering of the environment, provided by a lamp whose color is within the range of permissible chromaticity coordinates, allows the driver to properly see objects, obstacles, pedestrians, etc. when conducting this maneuver. Based on the chromaticity plot provided by Weldon for this lamp, the lamp color is outside the white boundary as required by FMVSS No. 108. NHTSA does not agree with Weldon's arguments that the color of light emitted by backup lamps is inconsequential to safety. With respect to Weldon's argument related to granting other petitions where a deviation from the requirement is not perceptible to the human eye and/or did not affect the illumination or brightness of the lamp, Weldon states in its own petition that in the subject noncompliance, there is a noticeable difference between the compliant lamp and the noncompliant lamp when viewed side-by-side.

Equally important, NHTSA does not find Weldon's arguments concerning NHTSA's past decisions related to the research documented in the ''Driver Perception of Just Noticeable Differences of Automotive Signal Lamp Intensities'' paper relevant to this petition since the application of the study is limited to luminous intensity of signal lamps and irrelevant to color requirements.

VII. NHTSA's Decision

In consideration of the foregoing, NHTSA has decided that Weldon has not met its burden of persuasion that the subject FMVSS No. 108 noncompliance is inconsequential to motor vehicle safety. Accordingly, Weldon's petition is hereby denied and Weldon is consequently obligated to provide notification of and free remedy for that noncompliance under 49 U.S.C. 30118 and 30120.

(Authority: 49 U.S.C. 30118, 30120: Delegations of authority at 49 CFR 1.95 and 501.8)

Anne L. Collins,

Associate Administrator for Enforcement.

[FR Doc. 2022–02311 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–59–P

[7] *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).

[8] *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21666 (Apr. 12, 2016).

[9] *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'').

[10] *See 49 CFR 571.108 S4.*

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2021–0118]

Pipeline Safety: Request for Special Permit; Florida Gas Transmission Company, LLC

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice.

SUMMARY: PHMSA is publishing this notice to solicit public comments on a request for a special permit received from the Florida Gas Transmission Company, LLC (FGT). The special permit request is seeking relief from compliance with certain requirements in the federal pipeline safety regulations. At the conclusion of the 30-day comment period, PHMSA will review the comments received from this notice as part of its evaluation to grant or deny the special permit request.

DATES: Submit any comments regarding this special permit request by March 7, 2022.

ADDRESSES: Comments should reference the docket number for this special permit request and may be submitted in the following ways:

- *E-Gov website: http://www.Regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: 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:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please submit two (2) copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov.*

Note: There is a privacy statement published on *http://www.Regulations.gov.* Comments, including any personal information provided, are posted without changes or edits to *http://www.Regulations.gov.*

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI.

Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Kay McIver, DOT, PHMSA–PHP–80, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or by email at *kay.mciver@dot.gov.*

Technical: Mr. Steve Nanney by telephone at 713–272–2855, or by email at *steve.nanney@dot.gov.*

SUPPLEMENTARY INFORMATION: PHMSA received a special permit request from FGT seeking a waiver from the requirements of 49 CFR 192.611(a) and (d): Change in class location: Confirmation or revision of maximum allowable operating pressure, and 49 CFR 192.619(a): Maximum allowable operating pressure: Steel or plastic pipelines.

This special permit is being requested in lieu of either a pipe replacement, pressure reduction, or new pressure test for two (2) special permit segments totaling 5,162 feet (approximately 0.978 miles) in total length of pipe. The pipeline special permit segments consist of the following:

- *Brevard County, Florida*—1,043 feet of 26-inch diameter Mainline Loop STA 18—STA 19 Pipeline, Class 1 to 3 location change, operates at a maximum allowable operating pressure (MAOP) of 977 pounds per square inch gauge (psig) and was constructed in 1968. The existing pipe design is for a Class 1 location. This proposed special permit segment is located approximately ½-mile south of the North Wickham Road crossing of Interstate 95 as shown on the map in Docket No. PHMSA–2021–0118.
- *Brevard County, Florida*—4,119 feet of 26-inch diameter Mainline Loop STA 18—STA 19 Pipeline, Class 1 to 3 location change, operates at an MAOP of 977 psig and was constructed in 1968. The existing pipe design is for a Class 1 location. This proposed special permit segment is located approximately 1-mile south of the North Wickham Road crossing of Interstate 95 as shown on the map in Docket No. PHMSA–2021–0118.

The special permit request, proposed special permit with conditions, and draft environmental assessment (DEA) for the FGT Mainline Loop STA 18—STA 19 Pipeline are available for review and public comments in Docket No. PHMSA–2021–0118. PHMSA invites interested persons to review and submit comments on the special permit request and DEA in the docket. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted. Comments may include relevant data.

Before issuing a decision on the special permit request, PHMSA will evaluate all comments received on or before the comments closing date. Comments received after the closing date will be evaluated, if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment it receives in making its decision to grant or deny this special permit request.

Issued in Washington, DC, on January 21, 2022, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2022–02344 Filed 2–3–22; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

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 information collection requirements related to Clear Reflection of Income in the Case of Hedging.

DATES: Written comments should be received on or before April 5, 2022 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 *omb.unit@irs.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Sara Covington, at (202) 317–4542, 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: Clear Reflection of Income in the Case of Hedging Transactions.

OMB Number: 1545–1412.

Regulation Project Number: FI–54–93 (TD 8554).

Abstract: This regulation provides guidance to taxpayers regarding when gain or loss from common business hedging transactions is recognized for tax purposes and requires that the books and records maintained by a taxpayer disclose the method or methods used to account for different types of hedging transactions.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 110,000.

Estimated Time per Respondent: 12 minutes.

Estimated Total Annual Burden Hours: 22,000.

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: February 1, 2022.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2022–02396 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee: VA National Academic Affiliations Council, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that a meeting of the VA National Academic Affiliations Council (NAAC) will be held March 9, 2022–March 10, 2022 at the American Legion, 7th Floor, 1608 K Street NW, Washington, DC 20006. The meeting is open to the public.

The purpose of the Council is to advise the Secretary on matters affecting partnerships between VA and its academic affiliates.

On March 9, 2022, the Council will convene an open session from 1:00 p.m. to 5:00 p.m. EST. The agenda will include collaborative discussions with Office of Research and Development leadership; Discovery, Education and Affiliate Networks leadership; and the Secretary of Veterans Affairs. The Council will receive a brief on Veterans Health Administration's Electronic Health Record Modernization efforts as related to education and research; and an update from the Strategic Academic Advisory Council.

On March 10, 2022, the Council will convene an open session and receive presentations on Federal Supremacy, the CHIP IN for Veterans Act's 10-year pilot program, and updates from Nursing education regarding residency programs, and the NAAC's Diversity in the Healthcare Workforce Subcommittee. The Council will receive public comments from 1:30 p.m. to 1:45 p.m. EST and will adjourn the meeting at 2:00 p.m.

Interested persons may attend and present oral statements to the Council. A sign-in sheet for those who want to give comments will be available at the meeting. Individuals who speak are invited to submit a 1–2 page summary of their comments at the time of the meeting for inclusion in the official meeting record. Oral presentations will be limited to five minutes or less, depending on the number of participants. Interested parties may also provide written comments for review by the Council prior to the meeting, or at any time via email to *Larissa.Emory@va.gov,* or by mail to Larissa Emory PMP, CBP, MS, Designated Federal Officer, Department of Veterans Affairs, Veterans Health Administration, Office of Academic Affiliations (14AA), 810 Vermont Avenue NW, Washington, DC 20420. Any member of the public wishing to attend or seeking additional information should contact Ms. Emory via email or by phone at (915) 269–0465.

Dated: January 31, 2022.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–02340 Filed 2–3–22; 8:45 am]

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FEDERAL REGISTER

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Part II

Securities and Exchange Commission

17 CFR Part 240

Prohibition Against Fraud, Manipulation, or Deception in Connection With Security-Based Swaps; Prohibition Against Undue Influence Over Chief Compliance Officers; Position Reporting of Large Security-Based Swap Positions; Proposed Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–93784; File No. S7–32–10]

RIN 3235–AK77

Prohibition Against Fraud, Manipulation, or Deception in Connection With Security-Based Swaps; Prohibition Against Undue Influence Over Chief Compliance Officers; Position Reporting of Large Security-Based Swap Positions

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rules.

SUMMARY: The Securities and Exchange Commission (''SEC'' or ''Commission'') is re-proposing for comment a rule under the Securities Exchange Act of 1934 (''Exchange Act''), which would be a new rule designed to prevent fraud, manipulation, and deception in connection with effecting transactions in, or inducing or attempting to induce the purchase or sale of, any security-based swap. The rule is designed specifically to take into account the unique features of a security-based swap and would explicitly reach misconduct in connection with the ongoing payments and deliveries that typically occur throughout the life of a security-based swap. The Commission also is proposing a new rule, which would make it unlawful for any officer, director, supervised person, or employee of a security-based swap dealer or major security-based swap participant, or any person acting under such person's direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the security-based swap dealer's or major security-based swap participant's chief compliance officer (''CCO'') in the performance of their duties under the federal securities laws or the rules and regulations thereunder. Finally, the Commission is using its authority under the Exchange Act to propose for comment a new rule, which would require any person with a security-based swap position that exceeds a certain threshold to promptly file with the Commission a schedule disclosing certain information related to its security-based swap position.

DATES: Comments should be received on or before March 21, 2022.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/regulatory-actions/how-to-submit-comments*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–32–10 on the subject line; or

Paper Comments

- Send paper comments to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–32–10. This file number should be included on the subject line if email is used. To help us 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/proposed.shtml*). Comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Room 1580, 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 the Commission does not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make publicly available.

Studies, memoranda, or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on the SEC's website. To ensure direct electronic receipt of such notifications, sign up through the ''Stay Connected'' option at *www.sec.gov* to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Carol M. McGee, Assistant Director, at (202) 551–5870, Office of Derivatives Policy, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–8010.

SUPPLEMENTARY INFORMATION: The Commission is re-proposing for comment 17 CFR 240.9j–1 (''Rule 9j–1'') under the Exchange Act, which would be a new rule designed to prevent fraud, manipulation, and deception in connection with effecting transactions in, or inducing or attempting to induce the purchase or sale of, any security-based swap. The Commission also is proposing new 17 CFR 240.15Fh–4(c) (''Rule 15Fh–4(c)'') under the Exchange Act, which would make it unlawful for any officer, director, supervised person, or employee of a security-based swap dealer or major security-based swap participant, or any person acting under such person's direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the security-based swap dealer's or major security-based swap participant's CCO in the performance of their duties under the Federal securities laws or the rules and regulations thereunder. Finally, the Commission is using its authority under Section 10B(d) of the Exchange Act to propose for comment new 17 CFR 240.10B–1 (''Rule 10B–1''), which would require any person with a security-based swap position that exceeds a certain threshold to promptly file with the Commission a schedule disclosing among other things: (1) The applicable security-based swap position; (2) positions in any security or loan underlying the security-based swap position; and (3) any other instrument relating to the underlying security or loan, or group or index of securities or loans. Proposed Rule 10B–1 includes different reporting thresholds for security-based swaps tied to debt securities and security-based swaps tied to equity securities. The Commission would make all filings received pursuant to proposed Rule 10B–1 available to the public, with the goal of increasing transparency and oversight in the security-based swap market.

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I. Introduction

A. Background

Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''),[1] which established a regulatory framework for the over-the-counter (''OTC'') derivatives market, provides that the Commission is primarily responsible for regulating security-based swaps, while the Commodity Futures Trading Commission (''CFTC'') is primarily responsible for regulating swaps. The Commission has now finalized a majority of its Title VII rules related to security-based swaps.[2] In accordance with those rules, a person who satisfies the definitions of ''security-based swap dealer'' (''SBSD'') or ''major security-based swap participant'' (''MSBSP'') (each SBSD and each MSBSP also referred to as an ''SBS Entity'' and together referred to as ''SBS Entities'') is now required to register with the Commission in such capacity and is therefore subject to the Commission's regime regarding margin, capital, segregation, recordkeeping and reporting, trade acknowledgment and verification requirements, risk mitigation techniques for uncleared security-based swaps, business conduct standards for security-based swap activity, including internal supervision requirements and the requirement to designate an individual to serve as the CCO who must take reasonable steps to ensure that the SBS Entity establishes, maintains, and reviews written policies and procedures reasonably designed to achieve compliance with the Exchange Act and the rules and regulations thereunder relating to its business as an SBS Entity.[3] Transaction reporting for security-based swaps has been required since November 8, 2021, with public dissemination to begin on February 14, 2022.[4]

In addition to the operational rules for SBS Entities and security-based swap data reporting and public dissemination, the Dodd-Frank Act also amended the Exchange Act in a number of important ways to prohibit fraud, manipulation, and deception in connection with security-based swaps. In particular, Section 763(g) of the Dodd-Frank Act expanded the anti-manipulation provisions of Section 9 of the Exchange Act to encompass purchases or sales of security-based swaps and requires the Commission to adopt rules to prevent fraud, manipulation, and deception in connection with security-based swaps. Specifically, paragraph (j) of Section 9 makes it unlawful for ''any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange, to effect any transaction in, or to induce or attempt to induce the purchase or sale of, any security-based swap, in connection with which such person engages in any fraudulent, deceptive, or manipulative act or practice, makes any fictitious quotation, or engages in any transaction, practice, or course of business which operates as a fraud or deceit upon any person.'' [5] It also provides that the Commission ''shall . . . by rules and regulations define, and prescribe means reasonably designed to prevent, such transactions, acts, practices, and courses of business as are fraudulent, deceptive, or

[1] Wall Street Transparency and Accountability Act of 2010, Public Law. 111–203, § 761–774, 124 Stat. 1376, 1754–1802(2010). Unless otherwise indicated, references to ''Title VII'' in this release are to Subtitle B of Title VII of the Dodd-Frank Act.

[2] *See, e.g.,* Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information, Exchange Act Release No. 74244 (Feb. 11, 2015), 80 FR 14563 (Mar. 19, 2015) (''2015 Regulation SBSR Adopting Release''); Security-Based Swap Data Repository Registration, Duties, and Core Principles, Exchange Act Release No. 74246 (Feb. 11, 2015), 80 FR 14437 (Mar. 19, 2015); Registration Process for Security-Based Swap Dealers and Major Security-Based Swap Participants, Exchange Act Release No. 75611 (Aug. 5, 2015), 80 FR 48963 (Aug. 14, 2015); Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information, Exchange Act Release No. 78321 (July 14, 2016), 81 FR 53545 (Aug. 12, 2016) (''2016 Regulation SBSR Adopting Release''); Applications by Security-Based Swap Dealers or Major Security-Based Swap Participants for Statutorily Disqualified Associated Person To Effect or Be Involved in Effecting Security-Based Swaps, Exchange Act Release No. 84858 (Dec. 19, 2018), 84 FR 4906 (Feb. 19, 2019); Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital and Segregation Requirements for Broker-Dealers, Exchange Act Release No. 86175 (June 21, 2019), 84 FR 43872 (Aug. 22, 2019) (''Capital, Margin, and Segregation Adopting Release''); Recordkeeping and Reporting Requirements for Security-Based Swap Dealers, Major Security-Based Swap Participants, and Broker-Dealers, Exchange Act Release No. 87005 (Sept. 19, 2019), 84 FR 68550 (Dec. 16, 2019) (''Recordkeeping and Reporting Adopting Release''); Rule Amendments and Guidance Addressing Cross-Border Application of Certain Security-Based Swap Requirements, Exchange Act Release No. 87780 (Dec. 18, 2019), 85 FR 6270 (Feb. 4, 2020) (''Cross-Border Amendments Release'').

[3] *See* Cross-Border Amendments Release, 85 FR at 6345–46. The first SBSDs were required to be conditionally registered with the Commission by November 1, 2021.

[4] *See* SEC Approves Registration of First Security-Based Swap Data Repository; Sets the First Compliance Date for Regulation SBSR (*available at: https://www.sec.gov/news/press-release/2021-80*). In addition, each registered security-based swap data repository (''SBSDR'') will be required to begin publicly disseminating security-based swap data as of February 14, 2022, which is the first Monday that is three months after the date that reporting began. *See* 2016 Regulation SBSR Adopting Release, 81 FR at 53608. Finally, the deadline for reporting certain historical security-based swaps to an SBSDR is two months after the date that public dissemination is required to begin (*i.e.,* April 14, 2022). *See* 2016 Regulation SBSR Adopting Release, 81 FR at 53610.

[5] *See* 15 U.S.C. 78i(j). Note that Section 9 of the Exchange Act erroneously contains two subsection (j)s.

manipulative, and such quotations as are fictitious.'' [6]

Additionally, Section 761 of the Dodd-Frank Act modified several definitions in both the Exchange Act and the Securities Act to account for security-based swaps. For example, the Dodd-Frank Act amended the definition of ''security'' in Section 3(a)(10) of the Exchange Act [7] and Section 2(a)(1) of the Securities Act [8] to include security-based swaps. As a result, security-based swaps, because they are securities, are subject to the general antifraud and anti-manipulation provisions of the Federal securities laws, including Sections 9(a), 10(b) and 17 CFR 240.10b–5 (''Rule 10b–5'') under the Exchange Act,[9] and Section 17(a) of the Securities Act.[10]

Moreover, the Dodd-Frank Act amended the definitions of ''purchase'' and ''sale'' in Section 2(a)(18) of the Securities Act,[11] the definitions of ''buy'' and ''purchase'' in Section 3(a)(13) of the Exchange Act,[12] and ''sale'' and ''sell'' in Section 3(a)(14) of the Exchange Act,[13] in the context of security-based swaps, to include the execution, termination, assignment, exchange, transfer, or extinguishment of rights or obligations. As a result of those changes, misconduct in connection with these actions will also be prohibited under Sections 9 and 10(b) of the Exchange Act and Rule 10b–5 thereunder, and Section 17(a) of the Securities Act.

Finally, the Dodd-Frank Act also amended the Exchange Act to explicitly authorize the Commission to require reporting of large security-based swap positions. Section 763(h) of the Dodd-Frank Act, entitled ''Position limits and position accountability for security-based swaps and large trader reporting,'' added Section 10B to the Exchange Act. In addition to providing the Commission with authority to establish position limits for security-based swaps, Section 10B(d) also provides the Commission with rulemaking authority to require reporting of large security-based swap positions. Specifically, Section 10B(d) authorizes the Commission to:

> . . . require any person that effects transactions for such person's own account or the account of others in any securities-based swap or uncleared security-based swap and any security or loan or group or narrow-based security index of securities or loans . . . to report such information as the Commission may prescribe regarding any position or positions in any security-based swap or uncleared security-based swap and any security or loan or group or narrow-based security index of securities or loans . . .[14]

On November 3, 2010, the Commission proposed for comment new Rule 9j–1, which would have prohibited the same categories of misconduct as Section 10(b) of the Exchange Act and Rule 10b–5 thereunder, and Section 17(a) of the Securities Act of 1933, in the context of security-based swaps, but would also have explicitly addressed misconduct that is in connection with the ''exercise of any right or performance of any obligation under'' a security-based swap.[15] In other words, the 2010 proposed rule would have applied to offers, purchases, and sales of security-based swaps in the same way that the general antifraud provisions apply to all securities, but also would have explicitly applied to the cash flows, payments, deliveries, and other ongoing obligations and rights that are specific to security-based swaps.[16]

The Commission has not yet finalized rules mandated by Section 9(j), nor has it proposed any reporting requirements pursuant to Section 10B(d) of the Exchange Act. The regulatory landscape for security-based swaps has changed since the Commission first proposed Rule 9j–1 in 2010. At the time, efforts to reform the global OTC derivatives markets, which had been set in motion in response to the 2008 financial crisis, had only begun, such that these markets were not yet subject to a comprehensive regulatory framework.[17] Since that time, however, regulators overseeing the world's primary OTC derivatives markets have made significant progress implementing reforms for OTC derivatives.[18] In addition to the progress made by the Commission in finalizing its Title VII rulemakings related to security-based swaps, the CFTC has largely completed its Title VII rulemakings related to swaps, including by adopting antifraud and anti-manipulation rules under the Commodity Exchange Act (''CEA'') to implement the Dodd-Frank Act's amendments to Section 6(c) of the CEA.[19] In light of the above, the Commission believes that now is an opportune time to move forward with the antifraud and manipulation rules required by Section 9(j) as well the rules contemplated by Section 10B(d). In addition, in recognition of the fact that CCOs of SBS Entities play an important role in preventing fraud and manipulation by SBS Entities and their personnel, in that they are tasked with designing and maintaining effective compliance systems, the Commission also is proposing an additional measure under Section 15F(h) of the Exchange Act to protect CCOs in the furtherance of those duties.[20]

B. Observations in the Credit Default Swap Market

In addition to the regulatory developments, there have been market developments. A number of press reports and academic articles since 2010

[6] *See id.*

[7] 15 U.S.C. 78c(a)(10).

[8] 15 U.S.C. 77b(a)(1).

[9] 15 U.S.C. 78j(b).

[10] 15 U.S.C. 77q(a).

[11] 15 U.S.C. 77b(a)(18).

[12] 15 U.S.C. 78c(a)(13).

[13] 15 U.S.C. 78c(a)(14).

[14] *See* 15 U.S.C. 78j–2(d).

[15] *See* Prohibition Against Fraud, Manipulation, and Deception in Connection with Security-Based Swaps, Exchange Act Release No. 63236 (Nov. 3, 2010), 75 FR 68560 (Nov. 8, 2010) (''2010 Rule 9j–1 Proposing Release''). For purposes of this release, we will refer to the version of Rule 9j–1 that the Commission proposed in the 2010 Rule 9j–1 Proposing Release as the ''2010 proposed rule.'' We will generally refer to Rule 9j–1 as we propose it here as the ''proposed rule'' or ''re-proposed Rule 9j–1.''

[16] *See* 2010 Rule 9j–1 Proposing Release, 75 FR at 68561–62.

[17] Commodity Futures Trading Commission and SEC Joint Report on International Swap Regulation, Jan. 31, 2012 (*available at: https://www.sec.gov/files/sec-cftc-intlswapreg.pdf*).

[18] *See* Financial Stability Board, OTC Derivatives Market Reforms: Note on implementation progress for 2010, Nov. 25, 2020 (*available at: https://www.fsb.org/wp-content/uploads/P251120.pdf*).

[19] 17 CFR 180.1 (''CFTC Rule 180.1'') implements the provisions of Section 6(c)(1) of the CEA by prohibiting, among other things, manipulative and deceptive devices employed intentionally or recklessly, regardless of whether the conduct in question was intended to create or did create an artificial price. CFTC Rule 180.1 also prohibits trading on the basis of material non-public information in breach of a pre-existing duty (established by another law or rule, agreement, understanding, or some other source) and trading on the basis of material non-public information that was obtained through fraud or deception. See 17 CFR 180.1. CFTC Rule 180.1(a) is modeled after Rule 10b–5 of the Exchange Act, although it contains some notable differences, such as its application to attempted fraud and manipulation. *Id.* 17 CFR 180.2 (''CFTC Rule 180.2''), promulgated pursuant to Section 6(c)(3) of the CEA and CFTC's general rulemaking authority, addresses price manipulation and, in line with Section 6(c)(3) of the CEA, provides that ''[i]t shall be unlawful for any person, directly or indirectly, to manipulate or attempt to manipulate the price of any swap, or of any commodity in interstate commerce, or for future delivery on or subject to the rules of any registered entity.'' A violation of CFTC Rule 180.2 requires a showing of ''specific intent.'' *See* Prohibition on the Employment, or Attempted Employment, of Manipulative and Deceptive Devices and Prohibition on Price Manipulation, 76 FR 41398, 41707 (Jul. 14, 2011) (''[the CFTC] reaffirms the requirement under final Rule 180.2 that a person must act with the requisite specific intent. In other words, recklessness will not suffice under final Rule 180.2 as it will under final Rule 180.1.'').

[20] To be clear, the ultimate responsibility for compliance by the SBS Entity with the federal securities laws, including the requirement to have adequate compliance systems and to avoid violations generally, rests with the SBS Entity itself.

have discussed manufactured credit events or other opportunistic strategies in the credit default swap (''CDS'') market.[21] Manufactured or other opportunistic CDS strategies can take a number of different forms but generally involve CDS buyers or sellers taking steps, with or without the participation of a company whose securities underlie, or are referenced by, a CDS (a ''reference entity''),[22] to avoid, trigger, delay, accelerate, decrease, and/or increase payouts on CDS.[23] Some examples reported by academics and the press include:

- A CDS buyer working with a reference entity to create an artificial, technical, or temporary failure-to-pay credit event in order to trigger a payment on a CDS to the buyer (and to the detriment of the CDS seller).[24]
- The strategy above (as well as other strategies) can be combined with causing the reference entity to issue a below-market debt instrument in order to artificially increase the auction settlement price for the CDS (*i.e.,* by creating a new ''cheapest to deliver'' deliverable obligation).[25]
- CDS buyers endeavoring to influence the timing of a credit event in order to ensure a payment (upon the triggering of the CDS) before expiration of a CDS, or a CDS seller taking similar actions to *avoid* the obligation to pay by ensuring a credit event occurs after the expiration of the CDS, or taking actions to limit or expand the number and/or kind of deliverable obligations in order to impact the recovery rate.[26]
- CDS sellers offering financing to restructure a reference entity in such a way that ''orphans'' the CDS—eliminating or reducing the likelihood of a credit event by moving the debts off the balance sheets of the reference entity and onto the balance sheets of a subsidiary or an affiliate that is not referenced by the CDS.[27]
- Taking actions, including as part of a larger restructuring, to increase (or decrease) the supply of deliverable obligations by, for example, adding (or removing) a co-borrower to existing debt of a reference entity, thereby increasing (or decreasing) the likelihood of a credit event and the cost of CDS.[28]

In June 2019, the former SEC Chairman, together with the principals of the CFTC and the U.K. Financial Conduct Authority at the time, issued a public statement stating that the ''continued pursuit of various opportunistic strategies in the credit derivatives markets, including but not limited to those that have been referred to as 'manufactured credit events,' may adversely affect the integrity, confidence and reputation of the credit derivatives markets, as well as markets more generally'' (''2019 Joint Statement'').[29] Additionally, in April 2018 the Board of Directors of ISDA stated their belief that ''narrowly tailored defaults . . . could negatively impact the efficiency, reliability and fairness of the overall CDS market.'' [30] Following this statement, in March 2019, ISDA introduced amendments to its Credit Derivatives Definitions designed to address certain issues related to manufactured credit events, which ISDA termed ''narrowly tailored credit events'' (''ISDA Amendments'').[31]

C. Overview of the Proposal

1. Re-Proposed Rule 9j–1

The Commission has decided to re-propose Rule 9j–1. As described in detail below, re-proposed Rule 9j–1 follows the same general approach as the 2010 proposed rule in that it would prohibit the same categories of misconduct as Section 10(b) of the Exchange Act and Rule 10b–5 thereunder, and Section 17(a) of the Securities Act of 1933 in the context of security-based swaps, including misconduct that is in connection with the exercise of any right or performance of any obligation under a security-based swap.[32] Unlike the 2010 proposed rule, however, this new proposal also includes an anti-manipulation provision similar to 17 CFR 108.2 (''CFTC Rule 180.2'').[33] Further, re-proposed Rule 9j–1 would provide that: (1) A person with material non-public information about a security cannot avoid liability under the securities laws by making purchases or sales in the security-based swap (as opposed to purchasing or selling the underlying security), and (2) a person cannot avoid liability under Section 9(j) or re-proposed Rule 9j–1 in connection with a fraudulent scheme involving a security-based swap by instead making purchases or sales in the underlying

[21] *See, e.g.,* Gina-Gail S. Fletcher, Engineered Credit Default Swaps: Innovative or Manipulative? 94 N.Y.U. L. Rev. 1073 (2019); *see also* Andras Danis & Andrea Gamba, Dark Knights: The Rise in Firm Intervention by CDS Investors, Ga. Inst. Of Tech. Scheller Coll. of Bus. Working Paper, Paper No. 3479635 & WBS Fin. Grp. Working Paper, Paper No. 265 (Nov. 2019) (*available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3479635*); *see also* Henry T.C. Hu, Corporate Distress, Credit Default Swaps, and Defaults: Information and Traditional, Contingent, and Empty Creditors, 13 Brook. J. Corp. Fin. & Com. L. 26–27 (Nov. 2018) (*available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3302816*).

[22] A security-based swap, including a CDS contract, may reference a number of different types of securities, including instruments of indebtedness, indices, interest rates, quantitative measures, or other financial or economic interests (each a ''reference obligation'').

[23] In order to cash settle any CDS contract that relies on the International Swaps and Derivatives Association (''ISDA'') standard documentation, a Credit Derivatives Determinations Committee (''DC'') must make a determination that a defined default event (a ''credit event'') occurred and vote to hold an auction to determine the settlement price of the CDS. A DC is generally composed of nine or ten dealers and five buy-side members. Once a DC determines that a credit event has occurred and that an auction should be held, the DC Secretary publishes auction terms, which include a list of obligations that a CDS protection buyer can deliver to the CDS protection seller after the auction settlement (each a ''deliverable obligation''). Each auction consists of two parts: (1) The first part of the auction, which involves submission of physical settlement requests by participating dealers, aims at determining the initial market mid-point, the net open interests, and adjustment amounts; and (2) the second part of the auction consists of calculating the final settlement price. Since a protection buyer has the right to deliver any of the deliverable obligations specified on the list, it is in the protection buyers' interest to deliver into the auction the cheapest deliverable obligation; as a result, the value of this ''cheapest to deliver'' deliverable obligation drives the final settlement price. *See* Markit and Creditex Credit Event Auction Primer, 1 (Feb. 2010) (*available at: http://www.creditfixings.com/information/affiliations/fixings/auctions/docs/credit_event_auction_primer.pdf); see also* Credit Suisse, A Guide to Credit Events and Auctions, Jan. 11, 2012, 5 (*available at: https://doc.research-andanalytics.csfb.com/docView?language=ENG&source=emfromsendlink&format=PDF&document_id=803733390&serialid=FWHCx3yCrSE3FoEvAbEKa6fRKhqLoKs0jL1gR5W2Dfs%3D*).

[24] *See* Hu, *supra* note 21 at 26–27.

[25] *See* Statement on Manufactured Credit Events by CFTC Divisions of Clearing and Risk, Market Oversight, and Swap Dealer and Intermediary Oversight (Apr. 24, 2018) (*available at: https://www.cftc.gov/PressRoom/SpeechesTestimony/divisionsstatement 042418*).

[26] *See* Hu, *supra* note 21 at 22–26.

[27] *See* Fletcher, *supra* note 21 at 1101.

[28] *See* Fletcher, *supra* note 21 at 1098. *See also* CFTC Talks Podcast, Credit Derivatives, (Jul. 10, 2019) (*available at: https://www.cftc.gov/Exit/index.htm?https://youtu.be/Qqo9KR6JXaM?*).

[29] *See* Joint Statement on Opportunistic Strategies in the Credit Derivatives Market (June 24, 2019) (*available at: https://www.sec.gov/news/press-release/2019-106*).

[30] *See* ISDA Board Statement on Narrowly Tailored Credit Events (April 11, 2018) (*available at: ISDA Board Statement on Narrowly Tailored Credit Events—International Swaps and Derivatives Association*).

[31] *See* Proposed Amendments to the 2014 ISDA Credit Derivatives Definitions Relating to Narrowly Tailored Credit Event (Mar. 6, 2019) (*available at: https://www.isda.org/2019/03/06/proposed-amendments-to-the-2014-isda-credit-derivatives-definitions-relating-to-narrowly-tailored-credit-events/*). On September 19, 2019, an update to the 2019 Joint Statement was issued. *See* Update to Joint Statement (Sept. 19, 2019) (*available at: https://www.sec.gov/news/public-statement/update-june-2019-joint-statement-opportunistic-strategies-credit-derivatives*). The updated statement welcomed ISDA's efforts, but also noted that the ISDA Amendments would not address all of the concerns identified in the 2019 Joint Statement, including but not limited to addressing opportunistic strategies that do not involve narrowly tailored credit events.

[32] *See* re-proposed Rule 9j–1(a) and (e).

[33] *See* re-proposed Rule 9j–1(b).

security (as opposed to purchases or sales in -the security-based swap).[34]

The Commission recognizes that CDS buyers and sellers regularly engage in legitimate interactions with reference entities, and often offer critical means of restructuring and funding for reference entities. Moreover, we also understand that CDS transactions are an important means by which debt holders hedge their underlying debt instruments, and that the absence of such hedging opportunities could impact prospective investors' willingness and ability to invest in that underlying market. The Commission preliminarily believes the proposal is sufficiently tailored to balance these concerns but, in section II.E below, is also soliciting comment on how it can address manufactured or other opportunistic strategies that involve fraudulent, deceptive, or manipulative activity, or that involve such quotations as are fictitious, without impairing the proper functioning of the security-based swap markets or other securities markets.

Further, the scope of re-proposed Rule 9j–1 is not limited to CDS. Fraudulent, deceptive, or manipulative conduct, such as providing false or incomplete information to a counterparty to secure better terms or pricing or to alter the performance of ongoing rights and obligations, has the potential to harm counterparties to all forms of swaps, including equity and non-CDS debt security-based swaps. Manipulation of the underlying reference security can affect the pricing of an equity or debt security-based swaps, as well as the ongoing payments and obligations that are based on the value of that reference security. Further, in some cases, particularly in instances involving security-based swaps transactions that are effected over the internet, there is a potential for trading software to distort pricing and payouts on security-based swaps.[35] Finally, to the extent an opportunistic strategy alters the operations of a reference entity, counterparties to any security-based swap based on that reference entity could be impacted; the potential harm is not limited to CDS holders. As a result, re-proposed Rule 9j–1 applies to all transactions in security-based swaps, consistent with the 2010 proposed rule.

2. Proposed Rule 15Fh–4(c)

The Commission also is proposing a rule aimed at protecting the independence and objectivity of an SBS Entity's CCO by preventing the personnel of an SBS Entity from taking actions to coerce, mislead, or otherwise interfere with the CCO. The Commission recognizes that SBS Entities dominate the security-based swap market and also recognizes the important role that CCOs of SBS Entities play in ensuring compliance by SBS Entities and their personnel with the federal securities laws. As a result, the Commission is proposing Rule15Fh–4(c) which would make it unlawful for any officer, director, supervised person, or employee of an SBS Entity, or any person acting under such person's direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the SBS Entity's CCO in the performance of their duties under the Federal securities laws or the rules and regulations thereunder.

3. Proposed Rule 10B–1

Finally, the Commission also recognizes that transparency can be beneficial to market participants so that they can act in an informed manner to protect their own interests. One example involves what some legal observers refer to as ''net-short debt activism''—where a market participant with a large CDS position and a controlling voting interest in the debt of a reference entity votes against its interest as a debt holder to ensure that a credit event occurs (such as by blocking a restructuring or voting against curing a technical default under the terms of a loan).[36] In such instances, both the Commission and relevant market participants—particularly issuers of the underlying debt securities—could benefit from having access to information that may indicate that one or more market participants has a financial incentive to take an action that would be harmful to the issuer, which in turn could impact the issuer's other security holders.[37] In particular, such notice would provide the relevant parties with the ability to take appropriate action to limit any potential harmful consequences. Given such benefits to the market, which may accrue even where the facts and circumstances of a particular situation are not indicative of potentially fraudulent, manipulative, or deceptive conduct, the Commission believes that public reporting of large CDS positions would help to provide such advance notice.

Additional transparency regarding large security-based swap positions also could alert market participants, including counterparties, as well as issuers of securities and their security holders, to the risk posed by the concentrated exposure of a counterparty. Such transparency also could enhance risk management by security-based swap counterparties and inform pricing of the security-based swaps. For example, if a single counterparty has a $5 billion security-based swap position distributed equally among five different dealers on the same underlying equity security, public reporting of that security-based swap position would alert each dealer to the total exposure of the reporting counterparty. In the event of an issue involving the underlying security or the counterparty's ability to make a payment on the security-based swaps composing the large position, some or all of those dealers could then take actions to protect their positions, such as increasing their hedges against the relevant security-based swaps or calling for additional margin, if permitted. Knowledge of the total position of a counterparty also may inform a dealer's actions in the event that the counterparty defaults on its obligations under the security-based swap.

Finally, transparency about security-based swap positions could play an important role in protecting market integrity, including by providing the Commission and other regulators with access to information that may indicate that a person (or a group of persons) is building up a large security-based swap position, which may be relevant for a number of reasons, as discussed in greater detail in section III. As previously discussed, the manufactured or other opportunistic strategies that have been reported to have taken place in the CDS markets take on a variety of

[34] *See* re-proposed Rule 9j–1(c) and (d).

[35] *See e.g.,* SEC Investor Alert: Binary Options Fraud available at: *https://www.investor.gov/protect-your-investments/fraud/types-fraud/binary-options-fraud.* (stating that the SEC has received numerous complaints alleging that certain ''internet-based binary options trading platforms manipulate the trading software to distort binary options prices and payouts.''). The SEC Investor Alert represents the views of the staff of the Office Investor Education and Advocacy. It is not a rule, regulation, or statement of the Commission. The Commission has neither approved nor disapproved its content. The SEC Investor Alert, like all staff statements, has no legal force or effect: It does not alter or amend applicable law, and it creates no new or additional obligations for any person. Depending on the facts and circumstances, binary options based on securities may be security-based swaps.

[36] *See* Joshua A. Feltman, Emil A. Kleinhaus, and John R. Sobolewski, Wachtell, Lipton, Rosen & Katz, The Rise of Net-Short Debt Activism, Harvard Law School Forum on Corporate Governance and Financial Regulation (Aug. 7, 2018) (*available at: https://corpgov.law.harvard.edu/2018/08/07/the-rise-of-the-net-short-debt-activist/*). *See also* Matt Levine, Aurelius Broke Windstream's Bonds to Save Them, Bloomberg View (Feb. 27, 2019).

[37] Harm to the issuer could lead to harm to its employees, customers, and business partners, among others. Any one of these indirect effects could create further harm to the issuer and its security holders.

forms. Although some of those strategies may have involved fraudulent or manipulative conduct, including those that involve parties acting to artificially inflate CDS payments, others do not necessarily constitute prohibited activity. The common thread to all of those strategies, however, is one or more parties taking affirmative steps to avoid, trigger, delay, accelerate, decrease, and/or increase payouts on CDS.[38] Given the importance of the CDS market and its interconnectedness with the underlying debt securities that CDS may be used to hedge, the Commission believes that additional transparency in the CDS market can help to ensure that it remains fair, orderly, and efficient. For similar reasons, such transparency also should benefit the market for other types of security-based swaps.

Accordingly, the Commission has decided to utilize its rulemaking authority under Section 10B of the Exchange Act to propose new Rule 10B–1, which would be a large trader position reporting rule for security-based swaps. Specifically, proposed Rule 10B–1 would require public reporting of, among other things: (1) Certain large positions in security-based swaps; (2) positions in any security or loan underlying the security-based swap position; and (3) positions in any other instrument relating to the underlying security or loan or group or index of securities or loans. As described in detail below, proposed Rule 10B–1 would, among other things, include a specific quantitative threshold for when public reporting is required.

The Commission recognizes that market participants are already subject to the requirements of 17 CFR 242.900 through 242.909 (''Regulation SBSR''), which governs regulatory reporting of security-based swap transactions to security-based swap data repositories (''SBSDRs'') and public dissemination of some of that transaction data pursuant to Section 13(m) of the Exchange Act.[39] Although both sets of requirements are intended to provide greater transparency in the security-based swap market, certain differences between the two highlight the need to propose Rule 10B–1. For example, pursuant to the statutory authority in Section 13(m)(1), Regulation SBSR requires real-time public reporting to SBSDRs and public dissemination of security-based swap *transaction* data but not of *position* data as is contemplated by Section 10B and proposed Rule 10B–1.[40] Although registered SBSDRs are required to establish, maintain, and enforce written policies and procedures reasonably designed to calculate positions for all persons with open security-based swaps for which the SBSDR maintains records,[41] they are not required to make those reports public.[42] As a result, any public position reporting pursuant to Regulation SBSR would need to be completely anonymous with respect to *both* the person building up large, concentrated security-based swap positions, and each of its counterparties. Finally, Regulation SBSR only requires reporting and public dissemination of security-based swaps, in contrast to Section 10B, which authorizes the Commission to require reporting of positions in both security-based swaps and *related* securities.[43] The Commission believes that requiring reporting of related securities serves an important function in allowing both the Commission and the public to develop a greater understanding of the impact that a large security-based swap position can have on the broader securities markets.

[38] *See* Fletcher, *supra* note 21 at 1098 (''[I]t is evident that engineered CDS transactions are unfair, create the perception of the market being rigged, and undermine the integrity of the market. . . . Fundamentally, parties enter into CDS expecting that the ultimate determination of whether the contract pays off rests with market forces, over which neither party has control. However, when a counterparty interferes and skews the outcome of the CDS contract to her benefit, she undercuts her counterparties' reasonable expectations and unjustly transfers wealth from her counterparty to herself.'').

[39] *See supra* note 4 and accompanying text (explaining that transaction reporting for security-based swaps has been required since November 8, 2021, with public dissemination to begin on February 14, 2022).

[40] *See, e.g.,* Section 13(m)(1)(C) of the Exchange Act, which provides that ''[t]he Commission is authorized to provide by rule for the public availability of security-based swap transaction, volume, and pricing data'' subject to certain conditions and requirements. 15 U.S.C. 78m(m)(1)(C).

[41] *See* 17 CFR 240.13n–5(b)(2).

[42] In fact, Section 13(m)(1)(C)(iii) of the Exchange Act provides that any Commission rulemaking pursuant to Section 13(m) (*i.e.,* Regulation SBSR) ''shall require real-time public reporting for [security-based swap] transactions, in a manner that does not disclose the business transactions and market positions of any person.'' *See* 15 U.S.C. 78m(m)(1)(C)(iii). By contrast, Section 10B(d), which is titled ''Large Trader Reporting,'' does not contain a limitation on disclosing the identity of security-based swap counterparties in connection with security-based swap *position* reporting. As discussed in section III, however, a person subject to the reporting requirements of proposed Rule 10B–1 would have to report its own identity and the size of its aggregate security-based swap position, but the person would not be required to report any information about its counterparties, including their identities.

[43] *See* supra note 14 and accompanying text.

II. Re-Proposed Rule 9j–1: Prohibition Against Fraud, Manipulation, and Deception in Connection With Security-Based Swaps

A. Prior Commission Action

As initially proposed in 2010, Rule 9j–1 would have prohibited the same categories of misconduct addressed by Section 10(b) of the Exchange Act [44] and Rule 10b–5 thereunder,[45] as well as Section 17(a) of the Securities Act,[46] but specifically in the context of security-based swaps. The 2010 proposed rule explicitly reached misconduct in connection with the ongoing payments and deliveries that are typical of security-based swaps, which occur throughout the life of the security-based swap.[47] Specifically, the 2010 proposed rule would have made it unlawful for any person, directly or indirectly, in connection with the offer, purchase or sale of any security-based swap, in the exercise of any right or performance of any obligation under a security-based swap, or the avoidance of such exercise or performance: (a) To employ any device, scheme, or artifice to defraud or manipulate; (b) to knowingly or recklessly make any untrue statement of a material fact, or to knowingly or recklessly omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; (c) to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (d) to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.[48]

Most commenters on the 2010 proposed rule generally supported the Commission's goal of adopting antifraud standards to ensure the integrity of the security-based swap market.[49] Some commenters expressed strong support for the 2010 proposed rule, stating that the rule would encourage investor confidence in the security-based swap market and would help ensure that the Commission has the ability to respond through enforcement mechanisms to

[44] 15 U.S.C. 78j(b).

[45] 17 CFR 240.10b–5.

[46] 15 U.S.C. 77q(a).

[47] 2010 Rule 9j–1 Proposing Release, 75 FR at 68561.

[48] 2010 Rule 9j–1 Proposing Release, 75 FR at 68568.

[49] The comment letters can be found at: *http://www.sec.gov/comments/s7-32-10/s73210.shtml.*

misconduct interfering with the independence and proper functioning of the market.[50] In addition, one commenter specifically requested that the Commission require disclosure of debt security-based swap positions.[51]

However, some commenters stated that the 2010 proposed rule exceeded the Commission's authority by addressing activities involving the exercise of any rights and performance of any obligations during the life of a security-based swap, as opposed to addressing only misconduct taking place in connection with the ''purchase'' and ''sale'' of a security-based swap.[52] Those commenters all generally argued that unless modified, the 2010 proposed rule would have a negative impact or chilling effect on the security-based swap market by unintentionally prohibiting the legitimate exercise of rights and performance of obligations under a security-based swap and by leading to costly unintended consequences. Section II.B.2. includes a discussion of the concerns raised by these commenters.

B. Scope of Re-Proposed Rule 9j–1

1. General Antifraud and Anti-Manipulation Provisions

The general antifraud and anti-manipulation provisions in re-proposed Rule 9j–1(a) would make it unlawful for any person, directly or indirectly, (i) to purchase or sell, or attempt to induce the purchase or sale of, any security-based swap; [53] (ii) to effect any transaction in, or attempt to effect any transaction in, any security-based swap; (iii) to take any action to exercise any right, or any action related to performance of any obligation, under any security-based swap, including in connection with any payments, deliveries, rights, or obligations or alterations of any rights thereunder; or (iv) to terminate (other than on its scheduled maturity date) or settle any security-based swap, in connection with which such person:

(1) Employs or attempts to employ any device, scheme, or artifice to defraud or manipulate; or

(2) Makes or attempts to make any untrue statement of a material fact, or omits to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or

(3) Obtains or attempts to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(4) Engages or attempts to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

Like the 2010 proposed rule, the current proposal generally relies on language from Section 10(b) of the Exchange Act [54] and Rule 10b–5 thereunder,[55] and Section 17(a) of the Securities Act,[56] as it relates to the specific types of fraudulent, manipulative, or deceptive conduct that re-proposed Rule 9j–1(a) is designed to address. In addition, re-proposed Rule 9j–1(a) describes the particular types of activity that would be covered by the rule, to the extent that a person engages in specified types of fraudulent, manipulative, or deceptive conduct in connection with such activities.[57] Specifically, the proposed rule would apply not only to the ''purchase'' or ''sale'' of security-based swaps, as such terms are defined in the Exchange Act,[58] but also to: (1) Effecting transactions, or attempts to effect transactions in, security-based swaps, (2) taking actions to exercise any right or actions related to performance of any obligation pursuant to any security-based swap including any payments, deliveries, rights, or obligations or alterations of any rights thereunder, or (3) terminating (other than on its scheduled maturity date) or settling any security-based swap, in connection with which such person engages in the specified fraudulent, manipulative, or deceptive conduct.

With respect to the operative paragraphs in re-proposed Rule 9j–1(a) describing the fraudulent, manipulative or deceptive conduct that the rule prohibits, those provisions have been structured to combine the antifraud and anti-manipulation provisions in Rule 10b–5 that apply to all securities (including security-based swaps) with the additional antifraud and anti-manipulative authority specific to security-based swaps provided to the Commission in Section 9(j). For example, re-proposed Rule 9j–1(a)(1) would explicitly prohibit employing or attempting to employ any device, scheme, or artifice to defraud or manipulate. Although most of that language is derived from Section 10(b) relies on the statutory authority in Section 9(j) of the Exchange Act, the Commission has determined to retain the language from the 2010 proposed rule that is based on an existing Exchange Act rule.

[50] *See, e.g.,* Letter from Laurel Leitner, Council for Institutional Investors, dated Dec. 16, 2010, at 1–2; Letter from Dennis Kelleher and Wallace Turbeville, Better Markets, dated Dec. 23, 2010, at 1–2; Letter from Chris Bernard, dated Nov. 21, 2010, at 1.

[51] *See* Letter from Suzanne H. Shatto, dated Jan. 27, 2011.

[52] *See* Letter from Stuart J. Kaswell, Managed Funds Association (''MFA''), dated Dec. 23, 2010 (''December 2010 MFA Comment Letter'') at 2–10; Letter from Stuart J. Kaswell, MFA, dated Mar. 29, 2011 (''March 2011 MFA Comment Letter'') at 3–9; Letter from Kenneth E. Bentsen, Jr., Securities Industry and Financial Markets Association (''SIFMA'') and Robert G. Pickel, ISDA, dated Dec. 23, 2010 (''SIFMA/ISDA Joint Comment Letter'') at 9–10, 13; Letter from Kenneth E. Bentsen, Jr., SIFMA, dated July 8, 2011 (''July 2011 SIFMA Comment Letter'') at 2–8; and Letter from R. Bram Smith, Loan Syndications and Trading Association (''LSTA''), dated Dec. 23, 2010 (''LSTA Comment Letter'') at 2–10.

[53] *See* proposed Rule 9j–1(e), which provides that the terms ''purchase'' and ''sale'' would have the same meaning as set forth in Sections 3(a)(13) and (14) of the Exchange Act. 15 U.S.C. 78c(a)(13) and (14).

[54] Section 10(b) of the Exchange Act provides that ''[i]t shall be unlawful for any person, directly or indirectly . . . (b) to use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.'' *See* 15 U.S.C. 78j(b).

[55] Rule 10b–5 under the Exchange Act provides that ''[i]t shall be unlawful for any person, directly or indirectly . . . (a) to employ any device, scheme, or artifice to defraud, (b) to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading, or (c) to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.'' *See* 17 CFR 240.10b–5.

[56] Section 17(a) of the Securities Act provides that ''[i]t shall be unlawful for any person in the offer or sale of securities . . . directly or indirectly—(1) to employ any device, scheme, or artifice to defraud, or (2) to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading, or (3) to engage in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser.'' *See* 15 U.S.C. 77q(a). In contrast to the 2010 proposed rule, the current proposal does not contain a provision based on Section 17(a)(2) of the Securities Act. Given that the current proposal itself

[57] *See* proposed Rule 9j–1(a). The introductory language in paragraph (a) follows Section 9(j) of the Exchange Act, in that it would prohibit specified activities *in connection with* which any person engages in the prohibited conduct set forth in paragraphs (1) through (4). By contrast, the corresponding language in the 2010 proposed rule followed the format used in Section 10(b) and applied solely to conduct that is *in connection with* the offer, purchase or sale of any security-based swap, the exercise of any right or performance of any obligation under a security-based swap, or the avoidance of such exercise or performance. The re-proposed language is intended to more closely track the authorizing statutory language in Section 9(j), and to make clear that under the proposed rule an activity would only be unlawful when done in connection with fraudulent, manipulative, or deceptive conduct.

[58] *See* proposed Rule 9j–1(e).

of the Exchange Act,[59] Rule 10b–5 thereunder,[60] and Section 17(a)(1) of the Securities Act,[61] the inclusion of ''manipulate'' and the extension of the prohibition to include an ''attempt'' to employ any device, scheme, or artifice to defraud or manipulate comes directly from the statutory authority in Section 9(j).[62] Paragraph (a)(2) of re-proposed Rule 9j–1, which prohibits the making of material misstatements or omissions, also is based on Rule 10b–5 and also contemplates an attempt to make a material misstatement or omission.

Finally, paragraphs (a)(3) and (4) of re-proposed Rule 9j–1 are based on Sections 17(a)(2) and (3) of the Securities Act.[63] Again, however, the re-proposed rule would now extend those provisions to attempted conduct, such that they would prohibit a person from (i) obtaining or attempting to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (ii) engaging or attempting to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

As the Commission explained in the 2010 Rule 9j–1 Proposing Release, the provisions described above have been designed generally to prohibit a range of fraudulent, manipulative and deceptive conduct in the security-based swap market, such as, among other things, ''engaging in fraudulent and deceptive schemes in order to increase or decrease the price or value of a security-based swap, or disseminating false or misleading statements that affect or otherwise manipulate the price or value of the reference underlying of a security-based swap for the purpose of benefiting such person's position in the security-based swap.'' [64] Re-proposed Rule 9j–1(a) also would prohibit, for example, disseminating false financial information or data in connection with the sale of a security-based swap or insider trading in a security-based swap. It also would prevent misconduct that affects the market value of the security-based swap for purposes of posting collateral or making payments or deliveries under such security-based swap.[65]

Re-proposed Rule 9j–1(a) also would prohibit fraudulent conduct in connection with a security-based swap that affects the value of cash flow, payments, or deliveries, such as by triggering the obligation of a counterparty to make a large payment or to post additional collateral. It would also prohibit a person from taking fraudulent or manipulative action with respect to the reference entity or asset of the security-based swap that triggers the exercise of a right or performance of an obligation or affects the payments to be made.[66]

Re-proposed Rules 9j–1(a)(1) and (2), consistent with Section 10(b) of the Exchange Act and Rule 10b–5 thereunder,[67] and Section 17(a)(1) of the Securities Act,[68] would require scienter.[69] In contrast, re-proposed Rules 9j–1(a)(3) and (4) would not require scienter consistent with Sections 17(a)(2) and (3) of the Securities Act.[70]

While both re-proposed Rules 9j–1(a)(2) and (3) would prohibit material misstatements and omissions,[71] they would address different levels of culpability.[72] Specifically, re-proposed

[59] *See supra* note 54.

[60] *See supra* note 55.

[61] *See supra* note 56.

[62] *See supra* note 5 and accompanying text. The application to attempted conduct also appears in other places in the Exchange Act and the rules and regulations thereunder. For example, Section 15(c)(1)(A) of the Exchange Act makes it unlawful for any broker-dealer ''to effect any transaction in, or to induce or attempt to induce the purchase or sale of, any security (other than commercial paper, bankers' acceptances, or commercial bills), or any security-based swap agreement by means of any manipulative, deceptive, or other fraudulent device or contrivance.'' 15 U.S.C. 78o(c)(1)(A). *See also* Commission Guidance Regarding Prohibited Conduct in Connection with IPO Allocations, Exchange Release No. 51500 (Apr. 7, 2005), 70 FR 19672, 19673 (Apr. 13, 2005) (''Regulation M applies to 'attempts,' thus proscribing a distribution participant's conduct irrespective of whether it actually results in market activity by others. It is the inducement or the attempt to induce during the restricted period that Regulation M prohibits.'') (internal citations omitted).

[63] *See supra* note 56.

[64] *See* 2010 Rule 9j–1 Proposing Release, 75 FR at 68569.

[65] *See id.*

[66] *See id.*

[67] To state a claim under Section 10(b) of the Exchange Act and Rule 10b–5, the Commission must establish that the misstatements or omissions were made with scienter. *See, e.g., Ernst & Ernst* v. *Hochfelder,* 425 U.S. 185, 193 (1976). The Supreme Court has defined scienter as ''a mental state embracing intent to deceive, manipulate or defraud.'' *Id.* Recklessness will generally satisfy the scienter requirement. *See, e.g., Sunstrand Corp.* v. *Sun Chemical Corp.,* 553 F.2d 1033, 1045 (7th Cir. 1977). *See also Greebel* v. *FTP Software, Inc.,* 194 F.3d 185, 198 (1st Cir. 1999); *SEC* v. *Environmental, Inc.,* 155 F.3d 107, 111 (2d Cir. 1998).

[68] Establishing violations of Securities Act Section 17(a)(1) requires a showing of scienter. *See, e.g., Aaron* v. *SEC,* 446 U.S. 680, 701–02 (1980). Scienter is the ''mental state embracing intent to deceive, manipulate or defraud.'' *Ernst & Ernst* v. *Hochfelder,* 425 U.S. 185, 193 (1976). *See also* Section 206(1) of the Investment Advisers Act of 1940 (''Advisers Act'), which makes it unlawful for an investment adviser to employ any device, scheme, or artifice to defraud any client or prospective client. 15 U.S.C. 80b–6(1). Claims arising under Section 206(1) of the Advisers Act require scienter. *See, e.g., Robare Grp. LTD* v. *SEC,* 922 F.3d 468, 472 (D.C. Cir. 2019); *SEC* v. *Moran,* 922 F. Supp. 867, 896 (S.D.N.Y. 1996); *Carroll* v. *Bear, Stearns & Co.,* 416 F. Supp. 998, 1001 (S.D.N.Y. 1976).

[69] The language in the 2010 proposed rule that corresponds to re-proposed Rule 9j–1(a)(2) included the phrase ''knowingly or recklessly'' when describing the prohibited conduct. The Commission has not included such phrase in the current proposal to remain consistent with similar language in Rule 10b–5. *See* 17 CFR 240.10b–5(b).

[70] Actions pursuant to Sections 17(a)(2) and 17(a)(3) of the Securities Act do not require a showing of scienter. *See, e.g., Aaron,* 446 U.S. at 701–02. In *Aaron,* the Supreme Court sought to determine whether scienter was required in a Commission injunctive proceeding pursuant to the antifraud provisions of Section 10(b) of the Exchange Act and Section 17(a) of the Securities Act. The Court examined the language of both sections and determined that scienter was required under Section 10(b) because the words ''manipulative,'' ''device,'' and ''contrivance,'' which are used in the statute, evidenced a Congressional intent to proscribe only knowing or intentional misconduct. Similarly, the Court concluded that subsection (1) of Section 17(a) required proof of scienter because Congress used such words as ''device,'' ''scheme,'' and ''artifice to defraud.'' *Aaron,* 446 U.S. at 696. In contrast, the Court concluded that the absence of such words under subsections (2) and (3) of Section 17(a) demonstrated that no scienter was required. Section 17(a)(2) prohibits any person from obtaining money or property ''by means of any untrue statement of a material fact or omission to state a material fact,'' which the Court found to be ''devoid of any suggestion whatsoever of a scienter requirement.'' *Aaron,* 446 U.S. at 696. Similarly, the Court found, in construing Section 17(a)(3), under which it is unlawful for any person ''to engage in any transaction, practice, or course of business which operates or would operate as a fraud or deceit,'' that scienter was not required because it ''quite plainly focuses upon the effect of particular conduct on members of the investing public, rather than upon the culpability of the person responsible.'' *Aaron,* 446 U.S. at 697. *See also* Section 206(2) of the Advisers Act, which makes it unlawful for an investment adviser to engage in any transaction, practice or course of business which operates as a fraud or deceit upon any client or prospective client. 15 U.S.C. 80b–6(2). The Commission is not required to demonstrate that an adviser acted with scienter in order to prove a Section 206(2) violation. *SEC* v. *Steadman,* 967 F.2d 636, 643 (D.C. Cir. 1992) (*citing SEC* v. *Capital Gains Research Bureau, Inc.,* 375 U.S. 180, 191–92 (1963)).

[71] Consistent with Section 10(b) of the Exchange Act, such misstatements and omissions must be material to be actionable. ''The question of materiality, it is universally agreed, is an objective one, involving the significance of an omitted or misrepresented fact to a reasonable investor . . . there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ''total mix'' of information made available.'' *TSC Indus., Inc.* v. *Northway, Inc.,* 426 U.S. 438, 445, 449 (1976). *See also Basic* v. *Levinson,* 485 U.S. 224, 233 (1988).

[72] In addition to differences in the standard of care, there are additional deviations between re-proposed Rules 9j–1(a)(2) and (3), notwithstanding the significant overlap in the rule text. For example, while paragraph (a)(2), like Rule 10b–5(b), makes it unlawful to make any untrue statement of a material fact, paragraph (a)(3), like Section 17(a)(2) of the Securities Act does not use the word ''make.'' Based on that difference courts have contrasted the application of Rule 10b–5(b) from the application of Section 17(a)(2) of the Securities Act as it relates

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Rule 9j–1(a)(2) would apply when there is evidence of scienter (*e.g.,* when a party to a security-based swap knowingly or recklessly makes a false statement even though the party may not receive any money or property as a result). In contrast, re-proposed Rule 9j–1(a)(3) would extend to conduct that is at least negligent (*e.g.,* when a party to a security-based swap knows or reasonably should know that a statement was false or misleading and directly or indirectly obtains money or property by means of such statement).

The Commission recognizes that two commenters to the 2010 proposed rule opposed not requiring scienter with respect to paragraphs (3) and (4) of re-proposed Rule 9j–1(a) (which were paragraphs (c) and (d) in the 2010 proposed rule). Specifically, SIFMA and ISDA argued that applying a negligence standard to those provisions did not account for the unique aspects of the security-based swap market and, when ''coupled with the rights and responsibilities provision and enforcement exposure for omissions of disclosure, potentially would make illegal a wide range of ordinary course activities that may relate to an SBS transaction.'' [73] Those commenters explained that ''[s]ubjecting every trading decision or payment under an SBS to an enforcement claim that someone knew or should have known that the action would operate as a fraud or deceit on a person could potentially deter many parties from entering into SBS, increase their cost and have other distorting effects on the markets.'' [74]

Although the Commission recognizes the concerns raised by these commenters, we have determined to re-propose Rule 9j–1(a) using the same standards of care as proposed in 2010. As previously noted, each of those provisions is based on an existing statutory and regulatory provision that is supported by a large body of case law.[75] In that respect, the Commission does not believe it is appropriate to treat negligent conduct that would have been deemed a violation under the existing antifraud and anti-manipulation provisions of the Federal securities laws and the rules and regulations thereunder as not violative under proposed Rule 9j–1(a) solely because security-based swaps contracts by their nature may require the counterparties to take ongoing actions to satisfy their rights and obligations. Such an approach would be particularly untenable in light of the fact that security-based swaps are included in the definition of ''security'', and therefore are also subject to such general antifraud and anti-manipulation provisions, including the relevant non-scienter-based prohibitions. To the extent that there is any overlap between re-proposed Rule 9j–1(a) and those existing provisions, introducing a different standard of care would create unnecessary confusion.

Moreover, having two nearly identical antifraud and anti-manipulation rules (*e.g.,* re-proposed Rule 9j–1(a)(1) and Rule 10b–5(b)) that are subject to two different standards of care—one for security-based swaps and one for other types of securities—is likely to lead to confusion among market participants and could potentially undermine the effectiveness of both provisions in certain circumstances, such as when the case law applicable to one provision contradicts the other in a way that is not able to be rationalized by the differences in the underlying instruments. Although the Commission preliminarily believes the re-proposed rule is not overly broad, in section II.E below, the Commission is requesting comment on whether there are potential ways to minimize the impact of the rule on non-fraudulent and non-manipulative ordinary course activities in connection with security-based swap transactions.

2. ''Purchases'' and ''Sales'' in the Context of Security-Based Swaps and Limited Safe Harbor for Certain Limited Actions

As previously noted, a number of commenters on the 2010 proposed rule argued that the Commission exceeded its statutory authority in the course of proposing Rule 9j–1 by explicitly applying the rule to activities involving the exercise of any rights and performance of any obligations during the life of a security-based swap, as opposed to limiting the proposed rule to misconduct taking place in connection with the ''purchase'' and ''sale'' of a security-based swap.[76] For example, MFA argued that the Commission exceeded delegated authority in proposing that the prohibitions in Rule 9j–1 extend ''beyond purchases and sales to acts and omissions occurring during the term of a security-based swap,'' explaining that ''[i]n clarifying the terms 'purchase' and 'sale' in the security-based swap context, Congress chose specifically not to include ongoing obligations, which are dictated by the contract between the two parties underlying the security-based swap and which bear no relation to execution, termination, assignment, exchange and transfer or extinguishment of rights.'' [77] MFA also expressed its view that ''Section 763(g) of Dodd-Frank is aimed at preventing fraudulent, deceptive, or manipulative acts in connection with: (i) The entry into a securit[y]-based swap; (ii) the novation or assignment of a securit[y]-based swap; and (iii) the unwind of a securit[y]-based swap,'' and that the statute should not be read to encompass the settlement of a security-based swap, or the ongoing payments or collateral postings that take place throughout the life of the transaction.[78]

Similarly, SIFMA and ISDA expressed the view that ''[t]he rulemaking authority provided by Section 763(g) only extends to transactions, acts, practices, or courses of business in connection with (i) effecting any transaction in [a security-based swap] and (ii) inducing or attempting to induce the purchase or sale of [a security-based swap].'' [79] SIFMA also separately shared its concerns that the application of proposed Rule 9j–1 to the ongoing, ''non-volitional'' rights and obligations that occur throughout the life of a security-based swap could be particularly problematic in the event that a counterparty came into possession of material non-public information relating to the underlying security, even if such information had no bearing on such non-volitional actions.[80] Further, the LSTA argued that

to determining who is the maker of a material misstatement. *See, e.g., SEC* v. *Big Apple Consulting USA, Inc.,* 783 F.3d 786, 797 (11th Cir. 2015) (''[W]e . . . agree with the Securities and Exchange Commission's recent opinion, which held '*Janus's* limitation on primary liability under Rule 10b–5(b) does not apply to claims arising under Section 17(a)(2).' ''); *SEC* v. *Tambone,* 597 F.3d 436, 444 (1st Cir. 2010) (en banc) (contrasting the language of Rule 10b–5(b) with ''the expansive language of section 17(a)(2),'' which covers ''the 'use' of an untrue statement of material fact (regardless of who created or composed the statement)'').

[73] *See* SIFMA/ISDA Joint Comment Letter at 12.

[74] *See* SIFMA/ISDA Joint Comment Letter at 3.

[75] *See supra* notes 67–71 and accompanying text.

[76] *See supra* note 52 and accompanying text.

[77] *See* December 2010 MFA Letter at 2–3. MFA provided examples of the types of ongoing obligations that it believed should not be covered by the rule, which included, among other things, certain periodic or other types of payments under the terms of the security-based swap as well as many forms of collateral or margin payments, and related obligations.

[78] *See* March 2011 MFA Comment Letter at 3–6.

[79] *See* SIFMA/ISDA Joint Comment Letter at 13.

[80] *See* July 2011 SIFMA Comment Letter at 2–7. SIFMA also requested that proposed Rule 9j–1 be modified to include a safe harbor, such as one that is similar to Rule 10b5–1(c)(2), which provides that an entity may demonstrate that a purchase or sale of securities is not ''on the basis of'' material non-public information if the person demonstrates that: (i) The individual making the investment decision on behalf of the person to purchase or sell the securities was not aware of the information; and (ii) the entity had implemented reasonable policies and procedures, taking into consideration the nature of the person's business, to ensure that individuals making investment decisions would not violate the

the 2010 proposed rule would ''create uncertainty that undermines investors' willingness to enter [the security-based swap] market,'' explaining that if the rule were to apply to any activity that potentially affects the stream of payments, deliveries or other ongoing obligations or rights between parties to a security-based swap, ''each party will have to implement controls and mechanisms to track decisions it may take that could affect each such payment, delivery, obligation or right as well as to track changes in its positions in the security-based swap and reference underlying.'' [81]

The Commission has carefully considered these comments, but disagrees with the narrow interpretation of the terms ''purchase'' and ''sale'' when used in the context of security-based swaps, as espoused by commenters. Specifically, the Commission does not believe that the definitions of ''purchase'' and ''sale'' in Section 2(a)(18) of the Securities Act, the definitions of ''buy'' and ''purchase'' in Section 3(a)(13) of the Exchange Act, and the definitions of ''sale'' and ''sell'' in Section 3(a)(14) of the Exchange Act are limited to actions involving *all* of the rights and obligations under a security-based swap. Rather, the Commission believes that those definitions incorporate partial executions, terminations, assignments, exchanges, transfers, or extinguishments of rights or obligations. Put another way, those definitions incorporate actions that have an impact on some, but not all, rights and obligations, such as a margin payment that represents only part of what one counterparty owes the other.

In addition, Congress could have specifically limited the statutory definitions of ''purchase'' or ''sale'' to actions involving *all* of the rights and obligations under a security-based swap, and the Commission, therefore, does not believe it necessary to apply limitations to those definitions that do not appear in the statute given that even partial payments or deliveries over the course of a security-based swap are likely to be meaningful to most security-based swap transactions. Accordingly, we continue to believe the statute provides the Commission with authority to make explicit the liability of persons that engage in misconduct to trigger, avoid, or affect the value of ongoing payments or deliveries as a means reasonably designed to prevent fraud, manipulation, and deception in connection with security-based swap transactions.

To be clear, the Commission is not taking the position that every payment or delivery made during the course of a security-based swap transaction is itself a purchase or sale of a security-based swap under the applicable statutory authority. Rather, fraudulent or manipulative conduct would be in connection with the purchase or sale of a security-based swap if it either alters any material terms of the security-based swap (as set forth in the applicable trading relationship documentation) or has a material impact on any payment or delivery under the security-based swap, such that it would not be consistent with what a reasonable person would have expected to pay, deliver, or receive absent such conduct. The Commission took a similar position when it defined certain Title VII terms, including ''swap'' and ''security-based swap,'' in a joint release with the CFTC, explaining that ''[i]f the material terms of a Title VII instrument are amended or modified during its life based on an exercise of discretion and not through predetermined criteria or a predetermined self-executing formula, the Commissions view the amended or modified Title VII instrument as a new Title VII instrument.'' [82] If a party engages in fraudulent or manipulative conduct that impacts the amount of payment or delivery in a way that is materially different from the amount a reasonable person would have expected to pay, deliver, or receive (or where such person would not have expected a payment or delivery to be required at all), such actions would be a new purchase or sale of the security-based swap. For example, and without limitation, such a scenario could involve a counterparty misstating certain information about a transaction (or any related transactions) resulting in a missed or late payment or loss of an opportunity to request additional collateral under a security-based swap.

Moreover, even if those statutory definitions were interpreted narrowly, the Commission's rulemaking authority under Section 9(j) of the Exchange Act to adopt prophylactic rules is not limited solely to purchases and sales of security-based swaps.[83] Section 9(j) of the Exchange Act provides that the Commission ''shall . . . by rules and regulations define, and prescribe means reasonably designed to prevent, such transactions, acts, practices, and courses of business as are fraudulent, deceptive, or manipulative, and such quotations as are fictitious.'' [84] Without limiting what is already covered by Section 9(j), the Commission is using that statutory authority to prohibit actions to exercise any right, or any action related to performance of any obligation, under any security-based swap, including in connection with any payments, deliveries, rights, or obligations or alterations of any rights thereunder; or to terminate (other than on its scheduled maturity date) or settle any security-based swap, in each case so long as those actions are taken in connection with fraud, manipulation, or deception. The Commission believes that by prohibiting actions that directly impact a counterparty's rights and obligations under a security-based swap—when such actions are in connection with specified fraudulent, manipulative, or deceptive conduct—re-proposed Rule 9j–1 represents a means reasonably designed to prevent fraud, manipulation, and deception in the security-based swap market.

Furthermore, in the course of using its rulemaking authority under Section 9(j), the Commission looked not only to the antifraud and anti-manipulation provisions in Section 10(b) of the Exchange Act, Rule 10b–5 thereunder, and Section 17(a) of the Securities Act, but also to the operative provisions of Section 9(j) itself, which makes it unlawful ''to effect any transaction in, or to induce or attempt to induce the purchase or sale of, any security-based swap, in connection with which such person engages in any fraudulent, deceptive, or manipulative act or practice, makes any fictitious quotation, or engages in any transaction, practice, or course of business which operates as

laws prohibiting trading on the basis of material non-public information. Such policies and procedures may include those that restrict any purchase, sale, and causing any purchase or sale of any security as to which the person has material non-public information, or those that prevent such individuals from becoming aware of such information. *See* 17 CFR 240.10b5–1(c)(2).

[81] *See* LSTA Comment Letter at 2–8. As an example, the LSTA noted its concern that a decision to allow a borrower to avoid a bankruptcy filing or payment default could be construed as manipulation in connection with the subsequent exercise of a right or performance of an obligation (whether such action is volitional or non-volitional).

[82] *See* Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping, 77 FR 48208, 48286 (Aug. 13, 2012) (''Products Release'').

[83] *See, e.g., U.S.* v. *O'Hagan,* 521 U.S. 642 (1997) (''[a] prophylactic measure, because its mission is to prevent, typically encompasses more than the core activity prohibited''). In *O'Hagan,* the Supreme Court held that under Section 14(e) of the Exchange Act (which includes the same ''reasonably designed to prevent fraudulent activity'' rulemaking language as Section 763(g) of the Dodd-Frank Act) the Commission may prohibit acts not themselves fraudulent under the common law or Section 10(b), provided that the prohibition is ''reasonably designed to prevent . . . acts and practices [that] are fraudulent.''

[84] *See* 15 U.S.C. 78i(j).

a fraud or deceit upon any person.'' At a minimum, that provision prohibits fraud, manipulation, or deception in the context of both inducements or attempts to induce the purchase or sale of a security-based swap, and effecting security-based swap transactions. As the Commission has previously explained in other contexts, ''effecting'' transactions in securities has been interpreted broadly and includes more than just executing trades or forwarding orders for execution.[85] Generally, effecting securities transactions also can include, for example, participating in the transactions through a number of activities such as screening potential participants in a transaction for creditworthiness, facilitating the execution of a transaction, and handling customer funds and securities.[86]

As discussed above, we disagree with the narrow interpretation of the statutory changes to the definitions of ''purchase'' and ''sale'' in the context of a security-based swap, as suggested by some commenters. That said, the Commission is sensitive to the operational concerns raised by commenters in response to the 2010 proposed rule and is therefore proposing two limited safe harbors from re-proposed Rule 9j–1(a) to address situations when a counterparty to a security-based swap is required to take certain actions while in possession of material non-public information.[87]

Specifically, re-proposed Rule 9j–1(f)(1) would provide that a person would not be liable under re-proposed Rule 9j–1(a) solely for reason of being aware of material non-public information while taking certain actions, the first of which includes actions taken in accordance with binding contractual rights and obligations under a security-based swap (as reflected in the written security-based swap documentation governing such transaction or any amendment thereto) so long as the person could demonstrate that: (1) The security-based swap was entered into, or the amendment was made, before the person became aware of such material non-public information; and (2) that the entry into, and the terms of, the security-based swap are themselves not a violation of any provision of re-proposed Rule 9j–1(a).[88] The Commission believes that limiting the safe harbor to circumstances where the activity is taken in accordance with the written agreements governing the security-based swap would help to ensure that such action is taken in the ordinary course of the transaction. Further, the safe harbor would apply only so long as the entry into, and the terms of, the security-based swap do not otherwise violate re-proposed Rule 9j–1.

As a result, the proposed safe harbor would generally apply to, for example, making a standardized coupon payment or delivering collateral to a counterparty (and would also permit the counterparty to receive the coupon payment or collateral), while such person is aware of material non-public information, so long as both actions are explicitly required by the terms of the transaction and documented in writing. However, the safe harbor would not apply if a counterparty took some action to fraudulently increase (in the case of the receiving counterparty) or decrease (in the case of the delivering counterparty) the amount of such payment or collateral transfer.

The second proposed safe harbor would apply to transactions effected pursuant to certain types of compression exercises. Specifically, proposed Rule 9j–1(f)(2) would provide that a person would not be liable under re-proposed Rule 9j–1(a) solely for reason of being aware of material non-public information when effecting security-based swap transactions pursuant to a bilateral portfolio compression exercise (as defined in 17 CFR 240.15Fi–1(a) (''Rule 15Fi–1(a)'') of the Exchange Act) or a multilateral portfolio compression exercise (as defined Rule 15Fi–1(j)) so long as: (1) Any such transactions are consistent with all of the terms of a bilateral portfolio compression exercise or multilateral portfolio compression exercise, including as it relates to, without limitation, the transactions to be included in the exercise, the risk tolerances of the persons participating in the exercise, and the methodology used in the exercise, and (2) all such terms were agreed to by all participants of the bilateral portfolio compression exercise or multilateral portfolio compression exercise prior to the commencement of the applicable exercise.[89]

As the Commission explained when it adopted portfolio compression requirements for SBS Entities, portfolio compression generally refers to a post-trade processing exercise that allows two or more market participants to eliminate redundant derivatives transactions within their portfolios in a manner that does not change their net exposure, and is intended to help market participants manage their post-traded risk.[90] For example, reducing the number of outstanding contracts provides important operational benefits and efficiencies for market participants in that there are fewer open contracts to

[85] *See* Registration Adopting Release, 80 FR at 48976, n. 99 (citing, for example, Definition of Terms in and Specific Exemptions for Banks, Savings Associations, and Savings Banks Under Sections 3(a)(4) and 3(a)(5) of the Securities Exchange Act of 1934, Exchange Act Release No. 44291 (May 11, 2001), 66 FR 27760, 27772–73 (May 18, 2001)).

[86] *See id.*

[87] Specifically, in its comment letter on the 2010 proposed rule, SIFMA explained that ''[u]nder the proposed rule, the counterparty would be required to disclose the [material non-public information] or abstain from performing its obligations under the contract, even though the [material non-public information] plays no role in its obligation to make payment. Requiring parties to ''disclose or abstain'' [material non-public information], as in the securities context, would leave market participants in the position of choosing among: Disclosing information to counterparties who may not want to know it because of the effect on their trading activity, violating the antifraud rule by performing their obligations under the SBS contract while in possession of [material non-public information] or abstaining from performance and defaulting on the contract.'' *See* July 2011 SIFMA Comment Letter at 3.

[88] *See* re-proposed Rule 9j–1(f)(1). In general, for uncleared security-based swap transactions, the relevant documentation should include the written security-based swap trading relationship documentation executed by the counterparties. For cleared security-based swap transactions, the relevant documentation should include the written agreement between the applicable counterparty and the clearing agency. For SBS Entities, existing 17 CFR 240.15Fi–5 (''Rule 15Fi-5'') requires each SBS Entity to establish, maintain, and follow written policies and procedures reasonably designed to ensure that it executes written trading relationship documentation with each of its counterparties, subject to certain exceptions, prior to, or contemporaneously with, executing a security-based swap transaction, in each case in the manner as provided for in the rule. That documentation is also subject to the Commission's recordkeeping requirements in 17 CFR 240.17a–4 or 17 CFR 240.18a–6, as applicable.

[89] *See* re-proposed Rule 9j–1(f)(2). Rule 15Fi–1(a) defines the term ''bilateral portfolio compression exercise'' to mean ''an exercise by which two security-based swap counterparties wholly terminate or change the notional value of some or all of the security-based swaps submitted by the counterparties for inclusion in the portfolio compression exercise and, depending on the methodology employed, replace the terminated security-based swaps with other security-based swaps whose combined notional value (or some other measure of risk) is less than the combined notional value (or some other measure of risk) of the terminated security-based swaps in the exercise.'' 17 CFR 240.15Fi–1(a). Rule 15Fi–1(j) defines the term ''multilateral portfolio compression exercise'' to mean ''an exercise by which multiple security-based swap counterparties wholly terminate or change the notional value of some or all of the security-based swaps submitted by the counterparties for inclusion in the portfolio compression exercise and, depending on the methodology employed, replace the terminated security-based swaps with other security-based swaps whose combined notional value (or some other measure of risk) is less than the combined notional value (or some other measure of risk) of the terminated security-based swaps in the exercise.'' 17 CFR 240.15Fi–1(j).

[90] *See* Risk Mitigation Techniques for Uncleared Security-Based Swaps, Exchange Act Release No. 87762 (Dec. 18, 2019), 85 FR 6359 at 6391 (Feb. 4, 2020) (''Risk Mitigation Adopting Release'').

manage, maintain, and settle, resulting in fewer opportunities for processing errors, failures, or other problems that could develop throughout the lifecycle of a transaction.[91] Given these important benefits, as well as the largely administrative nature of the portfolio compression process, the Commission believes it to be appropriate to provide a safe harbor for this activity in circumstances where the security-based swap counterparty is in possession of material non-public information with respect to a reference entity underlying an applicable security-based swap.

However, the proposed safe harbor would apply only so long as: (1) Any such transactions are consistent with all of the terms of a bilateral portfolio compression exercise or multilateral portfolio compression exercise, including as it relates to, without limitation, the transactions to be included in the exercise, the risk tolerances of the persons participating in the exercise, and the methodology used in the exercise, and (2) all such terms were agreed to by all participants of the bilateral portfolio compression exercise or multilateral portfolio compression exercise prior to the commencement of the applicable exercise. This condition, which the Commission believes is consistent with how portfolio compression exercises typically operate, is intended to help ensure that most, if not all, of the opportunities to take a discretionary action to impact the outcome of the compression exercise occur before the process begins, and therefore before specific security-based swap transactions are identified to be added or eliminated. Finally, this safe harbor, which is limited to circumstances involving the misuse of material non-public information, would not apply where the portfolio compression exercise itself was part of a fraudulent or manipulative scheme to increase (in the case of the receiving counterparty) or decrease (in the case of the delivering counterparty) the amount of any payment made or received in connection with a terminated or replacement security-based swap transaction resulting from the portfolio compression exercise, as applicable.

3. Prohibition on Price Manipulation

In addition to the general antifraud and anti-manipulation provisions discussed above, re-proposed Rule 9j–1 also contains provisions designed to address price manipulation similar to CFTC Rule 180.2.[92] Specifically, re-proposed Rule 9j–1 includes a prohibition on attempted manipulation. Re-proposed Rule 9j–1(b) would make it unlawful for any person to, directly or indirectly, manipulate or attempt to manipulate the price or valuation of any security-based swap, or any payment or delivery related thereto. Among other things, this language is intended to address a number of the manufactured or other opportunistic CDS strategies observed over the last decade, and summarized above in section I.B, including situations where a party intentionally distorts any payment related to a security-based swap for the benefit of one of the security-based swap counterparties, such as actions that serve little to no economic purpose other than to artificially influence the composition of the deliverable obligations in a CDS auction.[93]

Re-proposed Rule 9j–1(b) also is intended to prohibit, among other things, a situation where a person (or group of persons) improperly and intentionally causes or avoids the purchase or sale of a security-based swap for the benefit of a counterparty to an SBS, such as intentionally and improperly orphaning a CDS, avoiding termination of a CDS for a period of time, or causing the termination of a CDS. As previously noted, ''orphaning'' a CDS refers to a situation where the debt of a reference entity is eliminated or reduced for the purposes of moving the price of CDS.[94] The end result of such activity is that CDS buyers continue to pay (and CDS sellers continue to receive) premiums on CDS that will never default. Similarly, a CDS protection seller could offer financing to the company to avoid a credit event and subsequent CDS payout, with the financing timed so that the company's bankruptcy is merely delayed until after the CDS expires.[95] To be clear, a person simply profiting from a CDS position after a company's bankruptcy, which such person could have prevented by participating in a financing to the company, without more is not in and of itself improper conduct for purposes of re-proposed Rule 9j–1(b).

Moreover, the Commission does not intend for re-proposed Rule 9j–1(b) to apply to taking affirmative actions in the ordinary course of a security-based swap transaction or the underlying referenced security. Specifically, re-proposed Rule 9j–1(b) is designed to capture situations when a payment under the security-based swap is *intentionally distorted.* A determination as to whether a payment is intentionally distorted will largely depend on the facts and circumstances of each particular situation, but as a general matter the Commission would expect to use its authority to bring an enforcement action under re-proposed Rule 9j–1(b) when a party takes action for the purposes of avoiding or causing, or increasing or decreasing, a payment under a security-based swap in a manner that would not have occurred, but for such actions.

The Commission recognizes that reference entities often rely on financing and other forms of relief to avoid defaulting on their debt, and the proposed rule is not intended to discourage lenders and prospective lenders from discussing or providing such financing or relief, even when those persons also hold CDS positions. Rather, the Commission is proposing Rule 9j–1(b) to account for actions taken outside the ordinary course of a typical lender-borrower relationship (or a prospective lender-borrower relationship). Although any such determination would need to be based on the facts and circumstances of a particular situation, as a general matter the Commission believes that an action that appears to be designed almost exclusively to harm one or more CDS counterparties would likely fall within the prohibition in re-proposed Rule 9j–1(b).

C. Liability Under Proposed Rule 9j–1 in Connection With the Purchase or Sale of a Security

Finally, and consistent with the long-standing principle that parties cannot do indirectly what they are prohibited from doing directly, paragraphs (c) and (d) of re-proposed Rule 9j–1 would make it clear that market participants cannot avoid liability under the rule by effecting a fraudulent scheme through the purchase or sale of an underlying security, rather than the purchase or sale of the security-based swap on which it is based, and vice versa. The first of those two provisions would provide that a person could not escape liability for trading based on possession of material non-public information about a security by purchasing or selling a security-based swap based on that security (as opposed to trading in the security itself) and the second provision provides that a person could not escape liability under Section 9(j) or re-proposed Rule 9j–1 by purchasing or selling the underlying security (as opposed to purchasing or selling a security-based swap that is based on that security).

[91] *See id.*

[92] *See* 17 CFR 180.2.

[93] *See* Fletcher, *supra* note 21 at 1096–98.

[94] *See supra* note 27 and accompanying text.

[95] *See* Fletcher, *supra* note 21 at 1101.

Specifically, re-proposed Rule 9j–1(c) would provide that wherever communicating, or purchasing or selling a security (other than a security-based swap) while in possession of, material non-public information would violate, or result in liability to any purchaser or seller of the security, under either the Exchange Act or the Securities Act, or any rule or regulation thereunder, such conduct in connection with a purchase or sale of a security-based swap with respect to such security or with respect to a group or index of securities including such security shall also violate, and result in comparable liability to any purchaser or seller of that security under, such provision, rule, or regulation. Rule 9j–1(c) would be modeled after Section 20(d) of the Exchange Act, which is substantially similar to the proposal, except that the statutory provision applies to ''a put, call, straddle, option, privilege or security-based swap agreement''—*i.e.,* it does not expressly include the term security-based swap.[96]

Although the Commission generally believes that a situation where a person uses material non-public information in a security in connection with the purchase and sale of a security-based swap would be subject to the existing antifraud authority under the Federal securities laws, particularly Section 10(b) of the Exchange Act and Rule 10b–5 thereunder, the Commission also believes that market participants would benefit from a clarified interpretation of that statutory provision in this rulemaking.[97] This is particularly true given that the issuer of a security-based swap (*i.e.,* each counterparty to the transaction) is different from the issuer of the underlying security (*i.e.,* the reference entity). Accordingly, the Commission is now proposing new Rule 9j–1(c) to provide that a person making a purchase or sale of a security-based swap while in possession of material non-public information with respect to the security underlying such security-based swap is subject to liability.

Lastly, the Commission also is proposing new Rule 9j–1(d), which is intended to address a situation similar to the one described above, but in the other direction. Specifically, re-proposed Rule 9j–1(d) would provide that whenever purchasing or selling a security-based swap would violate, or result in liability under Section 9(j) of the Exchange Act or re-proposed Rule 9j–1(a) or (b), such conduct, when taken by a counterparty to such security-based swap (or any affiliate of, or a person acting in concert with, such security-based swap counterparty in furtherance of such prohibited activity), in connection with a purchase or sale of a security or group or index of securities on which such security-based swap is based shall also violate, and shall be deemed a violation of, Section 9(j) or re-proposed Rule 9j–1(a) or (b).

This provision is designed so that a person cannot escape liability under Section 9(j) or re-proposed Rule 9j–1(a) or (b) with respect to a security-based swap by limiting all of its actions to purchases and sales of the security or narrow-based security index underlying that security-based swap. For example, if a person with an existing total return swap on equity securities issued by XYZ Corporation subsequently engages in a number of wash trades to artificially inflate the price of the equity securities in order to benefit from the manipulated price by way of their existing security-based swap position, such person would be liable for violations of Section 9(j) and re-proposed Rule 9j–1 regardless of the fact the manipulation was conducted through purchases and sales of the equity securities.

To be clear, re-proposed Rule 9j–1(d) is not intended to create a separate category of prohibited activity. Rather, this provision is designed to specify that many of the activities that would be considered fraud, manipulation, or deceit with respect to a security-based swap are typically effected through transactions in the underlying reference entity, security, loan, or group or index of securities or loans. The Commission believes that this provision is important to include in the rule because security-based swaps by their nature are tied intrinsically to activity in other securities markets.

Moreover, this provision is not intended to suggest that a person could be liable for violations of Section 9(j) and re-proposed Rule 9j–1 based solely on the impact of its transactions on the equity, debt, or loan markets. In that regard, the rule would state that the person engaged in prohibited activities in the equity, debt, or loan markets must be a counterparty to a security-based swap that references such equity or debt securities or loans, or be an affiliate of, or a person acting in concert with, such security-based swap counterparty in furtherance of such prohibited activity. Finally, and in addition to analyzing whether transactions in the underlying equity or debt securities or loans have been used as the mechanism for violations of Section 9(j) and re-proposed Rule 9j–1, the Commission also would expect to analyze the same activities to determine whether they independently would also constitute violations under the existing antifraud and anti-manipulation provisions of the securities laws, including Sections 9 and 10(b) of the Exchange Act and Rule 10b–5 thereunder, as well as Section 17(a) of the Securities Act, as it relates the market for those underlying equity or debt securities or loans.

D. Preventing Undue Influence Over Chief Compliance Officers; Policies and Procedures Regarding Compliance With Re-Proposed Rule 9j–1, Proposed Rule 10B–1 and Proposed Rule 15Fh–4(c)

In addition to proposing rules to prevent fraudulent, manipulative, or deceptive conduct in connection with security-based swaps, the Commission also is proposing a rule aimed at protecting the independence and objectivity of an SBS Entity's CCO by preventing the personnel of an SBS Entity from taking actions to coerce, mislead, or otherwise interfere with the CCO. Specifically, new Rule 15Fh–4(c) would make it unlawful for any officer, director, supervised person, or employee of an SBS Entity, or any person acting under such person's direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the SBS Entity's CCO in the performance of their duties under the Federal securities laws or the rules and regulations thereunder.

The Commission previously considered whether to adopt a similar requirement when it adopted business conduct standards for SBS Entities in 2016.[98] That rulemaking included, among other things, 17 CFR 240.15Fk–1 (''Rule 15Fk–1''), which requires an

[96] *See* 15 U.S.C. 78t(d). Re-proposed Rule 9j–1(c) also differs from Section 20(d) in two other ways. First, the statutory provision refers to insider trading violations under the entirety of Title 15 of the U.S.C., the proposed rule refers only to the Exchange Act and the Securities Act, which are the two most common bases for asserting the Commission's authority for insider trading violations. Second, re-proposed Rule 9j–1(c) makes clear that the reference to a ''security'' does not include a security-based swap. This is intended solely to avoid confusion given that a security-based swap is included in the definition of ''security'' in Section 3(a)(10) of the Exchange Act [15 U.S.C. 78c(a)(10)] and Section 2(a)(1) of the Securities Act [15 U.S.C. 77b(a)(1)].

[97] Pursuant to Section 20(d), a person with material non-public information about a security cannot avoid liability under the securities laws by making purchases and sales in a swap on a broad-based index containing the security (*e.g.,* the S&P 500), which would be a security-based swap agreement, whereas the statute is silent as to the permissibility of trading on such material non-public information by making purchases and sales of a security-based swap (*e.g.,* a swap on the security itself).

[98] *See* Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants, Release No. 77617 (Apr. 14, 2016), 81 FR 29960 (''Business Conduct Standards Adopting Release'').

SBS Entity to designate a CCO and imposes certain duties and responsibilities on that CCO,[99] and Rule 15Fh–4(a), which makes it unlawful for an SBS Entity to: (i) Employ any device, scheme, or artifice to defraud any special entity or prospective customer who is a special entity; (ii) engage in any transaction, practice, or course of business that operates as a fraud or deceit on any special entity or prospective customer who is a special entity; or (iii) engage in any act, practice, or course of business that is fraudulent, deceptive, or manipulative.[100] In the course of that rulemaking, one commenter requested that the Commission adopt a rule prohibiting attempts by officers, directors, or employees to coerce, mislead, or otherwise interfere with the CCO.[101] The Commission considered that request, but ultimately concluded not to adopt such a rule, explaining that ''requiring a majority of the board to approve the compensation and removal of the CCO is appropriate to promote the CCO's independence and effectiveness. . . .'' [102]

Moreover, at the time the Commission declined to include a rule regarding undue influence over the CCO, the Commission had not yet finalized most of the requirements for which the CCO of an SBS Entity would be responsible and had not yet proposed rules relating to trading relationship documentation, dispute resolution, portfolio reconciliation or portfolio compression (''Risk Mitigation Rules'').[103] As the Commission explained when adopting the Risk Mitigation Rules, those rules were designed to further effective risk management by requiring the existence of sound documentation, periodic reconciliation of portfolios, rigorously tested valuation methodologies, and sound collateralization practices.[104] Attempts by officers, directors or employees to hide transactions, submit false valuations or manipulate or fraudulently influence the CCO in the performance of their duties related to the Risk Mitigation Rules would undermine the SBS Entity's risk management and could pose risk to the market.

In light of the re-proposal of Rule 9j–1 and the proposal of 10B–1 as well as the rules finalized subsequent to the CCO rules, the Commission believes it is appropriate to reconsider the need for a rule expressly prohibiting interference with the performance of a CCO's duties, even if not directly related to compensation or the threat of removal of the CCO to help ensure the independence and effectiveness of the CCO function.[105] In connection with re-proposed Rule 9j–1 and proposed Rule 10B–1, as well as other rules for which the CCO is responsible, undue influence could arise from many actors (and many actions), and not merely from those actors with the power to set compensation or with hiring and firing authority over the CCO. For example, an employee at an SBS Entity planning an opportunistic strategy could attempt to mislead the CCO by submitting false documentation to the CCO in order to avoid disclosing the build-up of a large position that would require public reporting and thwart the plans of the employee.

Although re-proposed Rule 9j–1 and proposed Rule 10B–1 apply to any person, without exception, and not just SBS Entities, as discussed in the Economic Analysis, the security-based swap market is dominated by dealers. The Commission estimates that dealing activity in security-based swap markets is highly concentrated among a small number of firms who are or will be registered with the Commission as SBS Entities.[106] Because of the concentration of security-based swap activities in a small number of firms that are SBS Entities, their compliance with the Federal securities laws, including those adopted since 2016 and any rules adopted as a result of this proposal, is critically important to fostering integrity in the security-based swap market.

Moreover, existing 17 CFR 240.15Fh–3(h) (''Rule 15Fh–3(h)'') requires an SBS Entity to establish and maintain a system to supervise its business and the activities of its associated persons which must be reasonably designed to prevent violations of the provisions of applicable Federal securities laws and the rules and regulations thereunder.[107] In addition, existing Rule 15Fk–1 requires an SBS Entity to designate a CCO, who must comply with certain duties, including to ''[t]ake reasonable steps to ensure that the [SBS Entity] establishes, maintains and reviews written policies and procedures reasonably designed to achieve compliance with the [Exchange Act] and the rules and regulations thereunder relating to its business as [an SBS Entity].'' [108] Failure to establish, maintain, and review written policies and procedures reasonably designed to achieve compliance with the Exchange Act and the rules and regulations thereunder (including re-proposed Rule 9j–1, and proposed rules 10B–1 and 15Fh–4(c) if adopted), may result in violations by the SBS Entity of Rule 15Fh–3(h), as well as Rule 15Fk–1.[109] Proposed Rule 15Fh–4(c) is designed to protect investors and promote the fairness of the markets by supporting the ability of the CCO to meet the CCO's important obligations to foster compliance without undue influence, which should ultimately support the integrity of SBS Entities and the markets.

E. Request for Comment

The Commission generally requests comments on all aspects of re-proposed Rule 9j–1. In addition, the Commission requests comments on the following specific issues:

[99] *See* 17 CFR 240.15Fk–1.

[100] *See* 17 CFR 240.15Fh–4(a).

[101] *See* Business Conduct Standards Adopting Release, 81 FR at 30053, n. 1166 and accompanying text.

[102] *See id.* at 30054–55.

[103] *See supra* note 2. The Commission first proposed the Risk Mitigation Rules in December 2018. *See* Risk Mitigation Techniques for Uncleared Security-Security-Based Swaps, Exchange Act Release No. 87782 (Dec. 19, 2018), 84 FR 4614 (Feb. 15, 2019).

[104] *See* Risk Mitigation Adopting Release, 85 FR at 6390.

[105] As the Commission explained when adopting similar rules prohibiting persons from unduly influencing auditors pursuant to Section 303(a) of the Sarbanes Oxley Act of 2002 (''Sarbanes-Oxley Act), activities by persons acting ''under the direction'' of officers and directors of the issuer ''currently may constitute violations of the antifraud or other provisions of the securities laws or aiding or abetting or causing an issuer's violations of the securities laws.'' *See* Improper Influence on Conduct of Audits, Exchange Act Release No. 47890 (May 20, 2003), 68 FR 31820, 31821 (May 28, 2003) (internal citations omitted). Nevertheless, like the rule implementing Section 303(a) of the Sarbanes-Oxley Act, proposed Rule 15Fh–4(c) would provide the Commission with an additional means of addressing efforts by persons acting under the direction of an officer or director to thwart the responsibilities of the CCO. *See also* Compliance Programs of Investment Companies and Investment Advisers, Investment Advisers Act Release No. 2204 (Dec. 17, 2003), 68 FR 74714 at 74721–22 (Dec. 24, 2003).

[106] *See infra* section VI.C.2. *See also* Applications by Security-Based Swap Dealers or Major Security-Based Swap Participants for Statutory Disqualified Associated Persons to Effect or Be Involved in Effecting Security-Based Swaps, Exchange Act Release No. 84858 (Dec. 19, 2018), 84 FR 4906, 4923 (Feb. 19, 2019) (''[t]he Commission estimates that dealing activity in security-based swap markets is highly concentrated among a small number of dealers, with the top five dealer accounts intermediating approximately 55 percent of all SBS Entity transactions, and reaching hundreds and even thousands of counterparties.'') (internal citations omitted).

[107] *See* 17 CFR 240.15Fh–3(h).

[108] *See* 17 CFR 240.15k–1. Additionally, in its application for registration, an SBS Entity is required to include a senior officer's certification that the SBS Entity has developed and implemented written policies and procedures reasonably designed to prevent violation of federal securities laws and the rules thereunder. *See* 17 CFR 240.15Fb2–1(b) (''Rule 15Fb2–1(b)'').

[109] The SBS Entity could also face liability under Rules 15Fb2–1(b) and (h) under such circumstances.

• Do commenters agree or disagree with any particular aspects of re-proposed Rule 9j–1? If so, which ones and why? If commenters disagree with any provision of the re-proposed rule, how should such provision be modified and why?

• As noted in section I.A, the existing antifraud and anti-manipulation provisions of the securities laws, including Sections 9 and 10(b) of the Exchange Act and Rule 10b–5 thereunder, as well as Section 17(a) of the Securities Act, already apply to security-based swaps because they fall within the definition of ''security'' in each of those statutes. Are there particular aspects of security-based swap transactions and the security-based swap markets that the Commission should specifically address? If so, does re-proposed Rule 9j–1 address those areas? If not, what types of fraudulent or manipulative activity, if any, might not be captured by the existing antifraud or anti-manipulation provisions or re-proposed Rule 9j–1, and how might new rules be drafted to address such activity?

• Do commenters agree with the inclusion and scope of the proposed safe harbors in re-proposed Rule 9j–1(f)? Why or why not? Should the actions permitted under the proposed safe harbor be limited solely to circumstances involving actions taken when a person is aware of material nonpublic information? Why or why not? Should the Commission include additional safe harbors in re-proposed Rule 9j–1 to address other types of ordinary course business activities, both in relation to a security-based swap transaction or any reference obligation? If so, how should the Commission define such activities?

• As discussed above, in response to operational concerns raised by commenters on the 2010 proposed rule, the Commission is proposing two limited safe harbors from re-proposed Rule 9j–1(a) to address situations when a counterparty to a security-based swap is required to take certain actions while in possession of material non-public information. Should the Commission also create a safe harbor for entering into security-based swap transactions for purposes of hedging some or all of their exposure arising out of lending activities with a reference entity or the syndication of such lending activities? Why or why not? If such a safe harbor is necessary, should ''hedging'' be defined and if so, how should it be defined? What types of activities should be included and/or excluded in such a safe harbor? What conditions should be included to protect other market participants and to ensure that any such safe harbor is not overly broad? For example, should the safe harbor require that a person using a security-based swap to hedge their interest in a loan while in possession of material nonpublic information provide certain information to their counterparty about the underlying borrower/reference entity? If so, what information should be required to be provided, and why? Should the safe harbor be conditioned on the person using a security-based swap to hedge their interest in a loan being a particular type of financial institution, such as a bank? Why or why not? Should the safe harbor be time limited, for example by requiring that the security-based swap be executed contemporaneously with the execution of the loan or the syndication of the loan? If so, how should such condition be structured? Could a safe harbor for hedging be constructed in a way to always distinguish legitimate hedging activity from other types of transactions? If so, how?

• As previously noted, re-proposed Rules 9j–1(a)(1) and (2), consistent with Section 10(b) of the Exchange Act and Rule 10b–5 thereunder, and Section 17(a)(1) of the Securities Act, require scienter. In contrast, re-proposed Rules 9j–1(a)(3) and (4) would not require scienter, consistent with Sections 17(a)(2) and (a)(3) of the Securities Act. Do commenters agree with the proposed standards of care in re-proposed Rule 9j–1(a)? Why or why not? If not, what should be the standard of care for each aspect of re-proposed Rule 9j–1(a) and why? Also, should the standard of care be different from the existing provision on which it was based, and if so, how and why? For example, if re-proposed Rules 9j–1(a)(1) and (2) continue to be based on Section 10(b) of the Exchange Act and Rule 10b–5 thereunder, and Section 17(a)(1) of the Securities Act, which require scienter, why should the proposed provisions rely on a different standard of care?

• One difference between re-proposed Rule 9j–1(a) and the 2010 proposed rule is that the four provisions based on Section 10(b) of the Exchange Act and Rule 10b–5 thereunder, and Section 17(a) of the Securities Act now refer to both actual conduct and *attempted* conduct. Do commenters agree with the change, as compared to the 2010 proposed rule, to extend those provisions in this manner? Why or why not?

• Do commenters agree with the application of re-proposed Rule 9j–1(a) to actions to exercise or any action related to performance pursuant to any security-based swap including any payments, deliveries, rights, or obligations or alterations of any rights thereunder; or to terminate (other than on its scheduled maturity date) or settle any security-based swap (in addition to, among other things, purchases or sales of, or actions to effect transactions in, security based swaps)? Why or why not?

• Re-proposed Rule 9j–1(a) differs from the 2010 proposed rule in that the current proposal is structured such that that the exercise of authority under the rule applies to certain specified actions being taken ''in connection'' with the fraudulent or manipulative conduct specified in paragraphs (1) through (4) of the re-proposed rule. By contrast, the 2010 proposed rule required that the fraudulent or manipulative conduct be ''in connection'' with the offer, purchase or sale of any security-based swap, the exercise of any right or performance of any obligation under a security-based swap, or the avoidance of such exercise or performance. The Commission is proposing the change to more closely track the language of Section 9(j) of the Exchange Act. Do commenters believe that this change better delineates the actions that would be subject to the rule or does it create confusion?

• Do commenters agree with the inclusion of re-proposed Rule 9j–1(b), which makes it unlawful for any person to, directly or indirectly, manipulate or attempt to manipulate the price or valuation of any security-based swap, or any payment or delivery related thereto? Why or why not? Should the Commission modify the proposed rule to expressly apply to the types of manufactured or other opportunistic behavior that have been occurring in the credit derivatives market and that are discussed in section II.B.3? If so, which ones and why? Are there additional types of manufactured or other opportunistic behavior that have been observed in the credit derivatives market that may be considered transactions, acts, practices, and courses of business that are fraudulent, deceptive, or manipulative, or involve such quotations as are fictitious? If so, which activities should be expressly prohibited and why?

• Re-proposed Rule 9j–1(c) would generally provide that a person could not avoid liability for insider trading by purchasing or selling a security-based swap while in possession of material non-public information with respect to a security or group or index of securities underlying such security-based swap if the person would otherwise have been liable had they purchased or sold the relevant securities. Do commenters agree with the inclusion of this provision? Why or why not? If not, how

should this provision be modified and why?

• Re-proposed Rule 9j–1(d) would generally provide that a person could not avoid liability under Section 9(j) of the Exchange Act or re-proposed Rule 9j–1 by purchasing or selling one or more securities underlying a security-based swap, as opposed to purchasing or selling the security-based swap itself if the person would otherwise have been liable under Section 9(j) of the Exchange Act or re-proposed Rule 9j–1 had they purchased or sold the security-based swap. Do commenters agree with the inclusion of this provision? Why or why not? If not, how should this provision be modified and why?

• Should the Commission adopt proposed Rule 15Fh–4(c), which would make it unlawful for any officer, director, supervised person, or employee of a security-based swap dealer or major security-based swap participant, or any person acting under such person's direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the security-based swap dealer's or major security-based swap participant's chief compliance officer in the performance of their duties under the Federal securities laws or the rules and regulations thereunder? Why or why not?

• Should proposed Rule 15Fh–4(c) only apply to officers or directors? Why or why not?

• Should proposed Rule 15Fh–4(c) apply to any person? Why or why not?

• Should proposed Rule 15Fh–4(c) be limited to actions to coerce, manipulate, or fraudulently influence the CCO? Should the proposed rule be limited to actions to mislead? Should the types of actions explicitly prohibited be expanded? If so, how and why?

• Should the Commission consider other means to protect the CCO in the performance of their duties?

• Should the Commission consider expanding proposed Rule 15Fh–4(c) to protect other officers of an SBS Entity in the performance of their duties? If so, which officers and why?

III. Proposed Rule 10B–1: Position Reporting of Large Security-Based Swap Positions

As previously noted, Section 10B of the Exchange Act, which provides the Commission with authority to establish position limits for security-based swaps, also provides the Commission with rulemaking authority to require reporting of large security-based swap positions. Specifically, Section 10B(d) authorizes the Commission to:

". . . require any person that effects transactions for such person's own account or the account of others in any securities-based swap or uncleared security-based swap and any security or loan or group or narrow-based security index of securities or loans . . . to report such information as the Commission may prescribe regarding any position or positions in any security-based swap or uncleared security-based swap and any security or loan or group or narrow-based security index of securities or loans and any other instrument relating to such security or loan or group or narrow-based security index of securities or loans . . ." [110]

The Commission has not previously proposed rules using its authority under Section 10B with respect to either position limits or reporting of large positions in security-based swaps. However, the Commission's observations of the security-based swap market suggest a number of potential benefits of requiring reporting. Those benefits, which are described in greater detail above in section I.C. include: (1) Providing market participants (including counterparties, issuers and issuers' stakeholders) and regulators with access to information that may indicate that a person (or a group of persons) is building up a large security-based swap position, which in some cases could be indicative of potentially fraudulent or manipulative purposes; (2) alerting market participants and regulators to the existence of concentrated exposures to a limited number of counterparties, which should inform those market participants and regulators of the attendant risks, allow counterparties to risk manage and lead to better pricing of the security-based swaps with respect to transactions with persons holding large positions in those security-based swaps; and (3) in the case of manufactured or other opportunistic strategies in the CDS market, providing market participants and regulators with advance notice that a person (or a group of persons) is building up a large CDS position which could create an incentive to vote against their interests as a debt holder, possibly with an intent to harm the company, even if such conduct is not inherently fraudulent.

Moreover, given that a number of these benefits accrue not only to the Commission, as the primary regulator of the security-based swap market (and potentially other regulators), but also to market participants (including reference entities), the Commission also believes that such reports should be made publicly available.[111] At the same time, however, the Commission understands that certain aspects of a security-based swap transaction may be sensitive or proprietary, particularly as they relate to a market participant's relationship with its counterparties, and accordingly we are not proposing to require reporting persons to publicly disclose any information about their counterparties, including their identities. Rather, under the proposed rule persons subject to the reporting requirement would only need to report the amount of their aggregated positions in a security-based swap on a single reference underlier, as well as any underlying or related positions.[112] However, to the extent that Commission staff believes it important to obtain counterparty information as part of our regulatory mission as it relates to one or more particular filings, staff would endeavor to obtain such information either directly from the filer (if so registered with the Commission) or from a registered SBSDR pursuant to Regulation SBSR.

Accordingly, the Commission is proposing to use its rulemaking

[110] *See* 15 U.S.C. 78j–2.

[111] *See supra* section I.C. Several academics discuss disclosure as a potential solution to some of the manufactured or other opportunistic CDS strategies described in section I.C. *See* Fletcher, *supra* note 21 at 1139–40 ("By requiring disclosure of plans to engage in an engineered CDS transaction, traders are able to reject counterparties that have indicated their intentions to intervene in the market. Alternatively, it allows CDS traders to decide if they want to charge or demand a higher price from the counterparty to offset the risk of loss. Disclosure, therefore, minimizes informational asymmetry between the counterparties, which would increase the cost of engineered transactions and in turn lower their profitability and their occurrence. Additionally, this disclosure requirement may also enhance market discipline, enabling CDS traders to avoid counterparties that might engage in engineered transactions or have done so in the past."). Other academics have made similar points in the broader context, some as far back as 2008. *See* Henry T.C. Hu and Bernard S. Black, Debt, Equity, and Hybrid Decoupling: Governance and Systemic Risk Implications, U of Texas Law, Law and Econ Research Paper No. 120, 31 (June 1, 2008) (". . . to address debt . . . decoupling, we propose . . . disclosure of their aggregate holdings of debt and debt derivatives"); *see also* Patrick Bolton and Martin Oehmke, Credit Default Swaps and the Empty Creditor Problem 24:8 Rev. Fin. Stud., 7 (Jan. 4, 2011) (". . . disclosure of CDS positions may mitigate the inefficiencies resulting from the empty creditor problem, without undermining the ex ante commitment effect of CDS. In particular, if public disclosure allows borrowers and lenders to contract on CDS positions, they may allow the lender to commit not to over-insure once he has acquired the bond. More generally, public disclosure of positions may also be beneficial by giving investors a more complete picture of creditors' incentives in restructuring."); *see also* Danis and Gamba, *supra* note 21 at 33 ("The CDS market is very opaque, and no regular investor knows how many protection sellers there are, how much protection they have sold, and whether they have deep pockets to inject cash into the underlying firm. Therefore, we argue that it is possible that regulation that improves the transparency of the CDS market can increase firm value. Other authors have proposed disclosure requirements in the CDS market as well . . . , although for different reasons.")

[112] *See infra* section III.B.

authority under Section 10B of the Exchange Act to propose a large trader position reporting rule for security-based swaps. That proposal is described in detail below.

A. Proposed Definitions and Thresholds

Proposed Rule 10B–1(a)(1) would require any person (and any entity controlling, controlled by or under common control with such person), or group of persons, who through any contract, arrangement, understanding or relationship, after acquiring or selling directly or indirectly, any security-based swap, is directly or indirectly the owner or seller of a Security-Based Swap Position that exceeds the Reporting Threshold Amount, to promptly file with the Commission a statement containing the information required by 17 CFR 240.10B–101 (''Schedule 10B'') on the Commission's Electronic Data Gathering, Analysis, and Retrieval system (''EDGAR'').[113] These reports would be made publicly available immediately upon filing.

Additionally, a person owns a Security-Based Swap Position by virtue of participation in a group of persons pursuant to any contract, arrangement, understanding or relationship, the proposed rule would provide that the group's filing obligation may be satisfied either by a single joint filing or by each of the group members making an individual filing.[114] If the group's members elect to make their own filings, each filing would be required to identify all members of the group, but the information provided concerning the other persons making the filing would need only to reflect information which the filing person knows or has reason to know.[115]

Moreover, the proposed rule also contains a provision intended to prevent evasion of the reporting requirement. Specifically, proposed Rule 10B–1(b)(4) provides that any person who, directly or indirectly, creates or uses a trust, proxy, power of attorney, pooling arrangement or any other contract, arrangement, or device as part of a plan or scheme to evade the reporting requirements of paragraph (a)(1) of this section with respect to a Security-Based Swap Position shall be deemed for purposes of this section to be the owner of such Security-Based Swap Position.[116] For example, if a number of entities agreed to acquire separate Security-Based Swap Positions that each fell below the relevant threshold in order to evade the requirement to report the larger, aggregated Security-Based Swap Position that exceeded the relevant threshold), proposed Rule 10B–1(a)(4) would deem each entity that was party to the arrangement to be the owner of the aggregated Security-Based Swap Position.

With respect to the scope of persons subject to this proposal, Section 10B provides the Commission with authority to require reporting by ''any person that effects transactions for such person's own account or the account of others [in security-based swaps and related financial instruments].'' [117] The Commission considered whether to limit this reporting requirement to certain types of persons, such as SBS Entities. However, and as described above, proposed Rule 10B–1 is ultimately intended to provide both the Commission and the market with information about any large positions in security-based swaps and any related securities that, in the event of a default, could have an impact on the markets, counterparties, or other market participants. This includes those positions that could adversely impact issuers of reference entities and their stakeholders, and those that could influence counterparties' risk management decisions or pricing of security-based swaps. Accordingly, the requirements in proposed Rule 10B–1 apply to ''any person,'' regardless of whether they are registered with the Commission in any capacity.

In terms of timing, proposed Rule 10B–1(a)(2) would provide that any Schedule 10B required by the rule shall be filed promptly, but in no event later than the end of the first business day following the day of execution of the security-based swap transaction that results in the Security-Based Swap Position first exceeding the Reporting Threshold Amount. That timing is consistent with the requirement in existing 17 CFR 240.15Fi–2(b) (''Rule 15Fi–2(b)''), which governs the timeframe for when an SBS Entity is required to provide a trade acknowledgment to its counterparty after executing a security-based swap transaction.[118] The Commission believes using a similar approach in proposed Rule 10B–1 is appropriate given that once a security-based swap transaction reaches the point when an SBS Entity is required to deliver a trade acknowledgment of a security-based swap to its counterparty, both sides to the transaction should then have the information about the size of the transaction so that each can determine whether any applicable Security-Based Swap Position has exceeded the Reporting Threshold Amount.[119]

Proposed Rule 10B–1 also contains key definitions for determining the scope of the position to be disclosed. In particular, the term ''Security-Based Swap Position'' would be defined to mean all security-based swaps based on: (a) A single security or loan, or a narrow-based security index, or any interest therein or based on the value thereof; (b) any securities issued by the

[113] *See* proposed Rule 10B–1(a). Because these position reports on proposed Schedule 10B would be made publicly available, the Commission is proposing to require them to be filed on EDGAR, similar to the way that beneficial ownership reports are filed pursuant to Sections 13(d) and (g) of the Exchange Act. *See* Rule 101(a)(1)(iii) of Regulation S–T (17 CFR 232.101(a)(1)(iii)) (requiring all statements, reports, and schedules filed with the Commission pursuant to Section 13 of the Exchange Act, among other provisions, to be submitted to the Commission in electronic form). If commenters believe that an alternate means of submission would be more appropriate, the Commission welcomes such feedback and encourages commenters to be as detailed as possible when specifying how such an alternative process would work, either in addition to or in lieu of the requirement to file proposed Schedule 10B on EDGAR.

[114] *See* proposed Rule 10B–1(a)(3).

[115] *See id.* The requirements related to the process for satisfying a group's filing obligations are similar to how the issue is addressed in 17 CFR 240.13d–1 (''Rule 13d–1''), which relates to the filing of Schedules 13D and 13G. Specifically, Rule 13d–1(k)(2) provides that ''[a] group's filing obligation may be satisfied either by a single joint filing or by each of the group's members making an individual filing. If the group's members elect to make their own filings, each such filing should identify all members of the group but the information provided concerning the other persons making the filing need only reflect information which the filing person knows or has reason to know.'' 17 CFR 240.13d–1(k)(2).

[116] *See* proposed Rule 10B–1(a)(4).

[117] *See* 15 U.S.C. 78j–2.

[118] *See* 17 CFR 240.15Fi–2(b).

[119] Rule 15Fi–2 also contains a second step once the applicable SBS Entity provides its counterparty with the required trade acknowledgment. Specifically, the rule also requires that the SBS Entity: (i) Establish, maintain, and enforce written policies and procedures that are reasonably designed to obtain prompt verification of the terms of a trade acknowledgment; and (ii) promptly verify the accuracy of, or dispute with its counterparty, the terms of a trade acknowledgment that it receives. *See* 17 CFR 240.15Fi–2(d). The Commission has determined to base the timing requirement in proposed Rule 10B–1 on the requirement to *deliver* a trade acknowledgment of a security-based swap, as opposed to the requirement to *verify* the trade acknowledgment due to the fact the rule does not require a counterparty that is not an SBS Entity to verify the trade acknowledgment. Rather, the regulatory obligation runs only to the SBS Entity, which is required to establish, maintain, and enforce written policies and procedures that are reasonably designed to obtain prompt verification of the terms of a trade acknowledgment. Moreover, while the Commission recognizes that the amount of the security-based swap transaction is clearly a term that would need to be resolved during the trade verification process if there is a dispute as to such value, the Commission believes that in most cases any such dispute would be resolved on a near real-time basis given the importance of that term as it relates to all of the other terms of the transaction.

same issuer (each, an ''issuing entity'') of the securities, loans, or securities included in the narrow-based index (including any interest therein or based on the value thereof) described in (a); or (c) any narrow-based security index that includes any of those issuing entities or their securities (including any interest therein or based on the value thereof), in each case as applicable.[120] To the extent that a Security-Based Swap Position is based on a single security or loan that is included in a narrow-based security index, the calculation of the Security-Based Swap Position with respect to a particular component of the index would be based on the weighting of the reference entity or securities as a component of the index. With respect to security-based swaps based on equity securities, a Security-Based Swap Position shall include all security-based swaps based on a single class of equity securities.[121]

Under this definition, a security-based swap that is based on a narrow-based security-index could trigger a reporting obligation under proposed Rule 10B–1 in two different ways. First, reporting under proposed Rule 10B–1 would be required if a person had a Security-Based Swap Position composed of security-based swaps based on a narrow-based security index that itself exceeded the relevant Reporting Threshold Amount. Second, if a person had a Security-Based Swap Position composed of security-based swaps based on a single security or loan, that person would need to include in the calculation of that position all security-based swaps based on the applicable single security or loan, in an amount proportionate to the weighting of the security or loan in the narrow-based security index. As a hypothetical example, if a person is a counterparty to a security-based swap on a narrow-based security index composed of equity securities with a notional amount of $100 million, the Security-Based Swap Position on the index itself would also be $100 million. In addition, if one security makes up 40% of that index by weight, that person would also be considered to have a Security-Based Swap Position of $40,000,000 attributable to such security for purposes of that transaction (which would need to be added to any other security-based swaps based on the same security in calculating the entire Security-Based Swap Position with respect such security).[122]

The Commission believes that the reporting requirement in proposed Rule 10B–1 should represent a person's *gross* position in a security-based swap [123] due to the fact that the proposed rule is intended to, among other things, identify circumstances when a market participant has a large, concentrated position in a security-based swap on a single issuer, which has the potential to impact not only the market for other security-based swaps on the same issuer, but also the applicable reference securities, even if that gross position consists of smaller positions that offset each other.[124] In such an instance, the gross position would be particularly informative where the offsetting positions are not with the same counterparty, where it may not be possible to net out any payment obligations between any two counterparties. For example, if a reporting person was long a total return swap with one counterparty and short a total return swap with a second counterparty (on the same reference equity security), a large decline in the price of the underlying security could trigger large payment obligations under both transactions, which could require one or more persons to liquidate some or all of the securities held to hedge the applicable total return swap. Under those circumstances, reporting the gross position would alert each of the two counterparties to the reporting person's overall exposure, which may be relevant to the extent that the counterparty to the other transaction is unable to satisfy its payment or delivery obligations.

The Commission also believes that requiring reporting of a person's aggregate Security-Based Swap Position (*i.e.,* all security-based swaps on the same reference entity, security, loan, or group or index of securities or loans that a person has with all their counterparties) is important for identifying positions that may have a significant impact on the person's counterparties, companies whose securities are referenced by a security-based swap, and the market as a whole, as discussed above in section I.C. For example, if a person has a large Security-Based Swap Position that is broken up between a number of different counterparties, reporting of the aggregated position could alert each individual counterparty to the fact that the reporting person also has significant exposure to other individual counterparties with respect to the same security-based swap.

For purposes of the definition of ''Security-Based Swap Position,'' security-based swaps based on a single class of equity securities issued by a reference entity would constitute a separate Security-Based Swap Position than security-based swaps based on debt securities of the same reference entity. A Security-Based Swap Position based on CDS also would constitute a separate Security-Based Swap Position.[125] As a result, there is a separate definition of ''Reporting Threshold Amount'' (as discussed in detail below) for Security-Based Swap Positions in each of: (i) CDS, (ii) debt security-based swaps (excluding CDS), and (iii) equity security-based swaps. For example, under that definition, a Security-Based Swap Position would include all security-based swaps on equity securities issued by XYZ Corporation, regardless of the fact that the position may be split among a number of counterparties. If the same reporting person also had CDS positions based on debt securities issued by XYZ Corporation, those CDS positions would constitute a separate Security-Based Swap Position. Lastly, if the same reporting person was also party to security-based swaps based on debt securities issued by XYZ Corporation that were not CDS, those transactions would constitute yet another separate Security-Based Swap Position.

However, proposed Schedule 10B would require the reporting party to report other securities (including other security-based swaps) that are related to the applicable Security-Based Swap Position.[126] Thus, if a reporting party has a Security-Based Swap Position composed of non-CDS security-based swaps on *debt* securities of XYZ Corporation that exceeds the relevant

[120] *See* proposed Rule 10B–1(b)(3).

[121] *See id.*

[122] As discussed below, for equity-based Security-Based Swap Positions the proposed rule would include both a notional threshold and a threshold based on the number of shares attributable to the Security-Based Swap Position. As a result, a person would need to convert the proportionate notional amount of a component security of a narrow-based security-index into a share count. In the above example, the notional amount of $40,000,000 would need to be converted into a share count using the methodologies set forth in proposed Rule 10B–1(b)(4). *See infra* section III.A.2.

[123] For purposes of this release, the term ''gross'' means the sum of the absolute values of notional amounts outstanding of all of the security-based swaps included in a Security-Based Swap Position. For example, if a person has a $75 million long CDS position and a $75 million short CDS position on the same reference entity or security, the person will have a Security-Based Swap Position of $150 million.

[124] As a hypothetical, if a person has a large, hedged position in an equity swap and is required to quickly liquidate its hedged positions in the reference securities in order to close out the security-based swap position, the transactions made to liquidate the reference securities could potentially impact the price of those securities depending on the size of the hedged position.

[125] *See id.*

[126] Section III.B. below discussed the information required to be included in proposed Schedule 10B.

threshold, as well as a Security-Based Swap Position composed of security-based swaps on *equity* securities of XYZ Corporation that does *not* exceed the threshold for reporting, such person would be required to report the debt-based Security-Based Swap Position on proposed Schedule 10B on which the person would need to report the equity-based security-based swaps as related securities.[127] If *both* the debt-based Security-Based Swap Position and the equity-based Security-Based Swap Position exceeded the applicable threshold, the reporting party would need to file a separate Schedule 10B for each position, which could cross-reference to the other filing for purposes of disclosing related securities.

1. Reporting Thresholds for Debt Security-Based Swaps (Including CDS)

Proposed Rule 10B–1(b)(1) sets forth the definition of ''Reporting Threshold Amount.'' That definition is bifurcated depending on whether the security-based swap is based on equity or debt, with a further delineation for CDS. For CDS (including CDS where the underlying reference is a group or index of entities or obligations of entities that is a narrow-based security index), the threshold is the lesser of: (i) A long notional amount of $150 million, calculated by subtracting the notional amount of any long positions in a deliverable debt security underlying a security-based swap included in the Security-Based Swap Position from the long notional amount of the Security-Based Swap Position; (ii) a short notional amount of $150 million; or (iii) a gross notional amount of $300 million.[128]

With respect to the $150 million long notional threshold for CDS positions, the Commission believes that a threshold that identifies parties with a significant naked CDS long exposure (or a CDS exposure that significantly exceeds its position in deliverable bonds) could help to more accurately identify situations where a CDS counterparty may be incentivized to act against their own interest as a debt holder (*i.e.,* because they stand more to gain from their CDS than they would lose on their bonds) which, as described above, is a possible indicator of an incentive to create a manufactured or other opportunistic credit event.[129] Put another way, if a bondholder uses long CDS positions solely to hedge their underlying bonds, payments received in connection with the CDS (upon a trigger) generally would be offset by losses on the bonds, leaving the person flat, and therefore not required to report under proposed Rule 10B–1. The Commission believes that $150 million, which again was based on staff's review of the available DTCC–TIW data,[130] appropriately captures naked CDS positions that carry the potential to be used in connection with a manufactured or other opportunistic credit event, even if such an activity would be unlikely to result in a broader impact on the CDS and bond markets.

The Commission also is proposing to use a $150 million notional threshold for short CDS positions. In particular, we believe that this threshold should capture situations where a CDS seller has a large enough position to potentially utilize an opportunistic strategy to avoid or delay a credit event, such as by ensuring a credit event occurs after the expiration of the CDS, or taking actions to limit the number and/or kind of deliverable obligations in order to impact the recovery rate following a credit event.[131] However, because the same dynamic described in the previous paragraph—vis-à-vis the potential motivations of a person with a significant naked CDS long exposure to vote against their own interests as a bondholder—may not exist in the case of a CDS seller, the $150 million notional threshold for short CDS positions does not include a provision allowing the reporting person to net out any deliverable bonds from the calculation.

Accordingly, the Commission is proposing a third threshold to capture the positions of market participants with significant gross CDS positions, notwithstanding the direction of the person's CDS positions or their positions in deliverable bonds. Specifically, the Commission believes that a gross CDS position that equals or exceeds $300 million would likely create enough counterparty concentration risk to potentially have other impacts on the market, even in the absence of a manufactured or other opportunistic credit event. As an example, if a person held $125 million in bonds on ABC Corporation and purchased $200 million in CDS on those bonds (or any other obligations that could be deliverable into an auction after a Credit Event), those two positions would offset each other, such that the net Security-Based Swap Position would be $75 million, and reporting pursuant to proposed Rule 10B–1 would not be required given that the net exposure falls below $150 million. By contrast, if a person held $250 million in bonds on ABC Corporation and purchased $325 million in CDS on those bonds, the person would be required to report that position pursuant to proposed Rule 10B–1 given that the gross Security-Based Swap Position exceeds $300 million, even though those two positions would offset each other to create a net $75 million exposure.

With respect to all other Security-Based Swap Positions based on debt securities (*i.e.,* not CDS), the Commission is proposing that the threshold be a gross notional amount of $300 million, without regard to direction of the person's CDS positions and without excluding any debt securities underlying a security-based swap included in the Security-Based Swap Position.[132] The Commission does not believe it to be appropriate to allow these positions to be netted against any underlying debt securities given that these types of security-based swap transactions operate differently than CDS transactions. For example, a CDS buyer whose security-based swaps are used to hedge some or all of their positions in an underlying bond will likely be less inclined to take actions that would result in a CDS default,

[127] As previously noted, Section 10B(d) provides the Commission with the authority to require ''any person that effects transactions for such person's own account or the account of others in any securities-based swap or uncleared security-based swap and any security or loan or group or narrow-based security index of securities or loans . . . to report such information as the Commission may prescribe regarding any position or positions in any security-based swap or uncleared security-based swap *and any security or loan or group or narrow-based security index of securities or loans and any other instrument relating to such security or loan or group or narrow-based security index of securities or loans . . .*'' *See* 15 U.S.C. 78j–2(d) (emphasis added).

[128] *See* proposed Rule 10B–1(b)(1)(i). These proposed thresholds are based, at least in part, on individual CDS exposure data from the Depository Trust and Clearing Corporation (''DTCC'') Trade Information Warehouse (''TIW''). This information is made available to the Commission voluntarily in accordance with an agreement between the DTCC–TIW and the OTC Derivatives Regulators' Forum, of which the Commission is a member. In reviewing the DTCC–TIW data, Commission staff attempted to identify notional amounts that would be low enough to capture any positions that could potentially have an effect on either the reference entity and/or the CDS or bond market (or both), yet also high enough to avoid over-reporting, which could limit the effectiveness of the rule. *See infra* section VI.D.2.iii. In developing these thresholds, staff also considered the opportunistic CDS strategies described in the relevant academic literature, and summarized in section I.C.

[129] *See supra* section I.C. Proposed Rule 10B–1(b)(1)(iv) provides that for purposes of the rule, a ''debt security underlying a security-based swap included in the Security-Based Swap Position'' means any security that could potentially be deliverable into a CDS auction in the event of a default.

[130] *See infra* section VI.D.2.iii.

[131] *See supra* note 26 and accompanying text.

[132] *See* proposed Rule 10B–1(b)(1)(ii).

given that the payment received should correspond to their losses from the bond. By contrast, a CDS buyer who does not hold the underlying bond may be incentivized to take actions that would result in a CDS default given that the resulting payment would not be offset by the buyer's losses from the bond. Such a dynamic—*i.e.,* where there are conflicting motivations as between the CDS transaction and any debt securities underlying that CDS transaction—is less likely to occur in connection with other types of security-based swaps.[133] For similar reasons, the threshold for these types of security-based swaps also does not include a lower threshold for long and short positions.

2. Reporting Threshold for Security-Based Swaps on Equity

For Security-Based Swap Positions based on equity securities, the Commission is proposing that the ''Reporting Threshold Amount'' in proposed Rule 10B–1(b)(1) be bifurcated, such that it would be defined to include both a threshold based on the notional amount of the Security-Based Swap Position, and a threshold based on the total number of shares attributable to the Security-Based Swap Position as a percentage of the outstanding number of shares of that class of equity securities. Those thresholds, which are specified below, are based on a review of all available information, including the data the Commission collects from Form N–PORT, which requires certain registered investment companies to report information about their monthly portfolio holdings to the Commission.[134] As with the threshold for Security-Based Swap Positions based on CDS, these thresholds were constructed to be low enough to capture any positions that could potentially have a significant effect on the equities markets, and potentially issuers of equity securities and their security holders, yet also high enough to avoid over-reporting, which could limit the effectiveness of the rule. In other words, the Commission has endeavored to set these thresholds at a level that should limit the reporting burden to include only those positions that are most likely to achieve the underlying purposes of the rule.

As of November 8, 2021, the Commission now has access to additional equity security-based swap transaction data from registered SBSDRs pursuant to Regulation SBSR.[135] In addition, equity securities are more widely traded in the secondary markets than debt securities, such that trading volume could be a key metric for measuring the potential market impact of a large equity swap position but not as relevant a metric for measuring the potential market impact of a large CDS position. The Commission intends to consider this newly available data in determining thresholds to use in connection with Security-Based Swap Positions based on equity securities when adopting a final rule.

Notional Threshold

Pursuant to proposed Rule 10B–1(b)(1)(iii), the term ''Reporting Threshold Amount'' with respect to Security-Based Swap Positions on equity securities is defined to mean the *lesser* of two different thresholds, one based on the notional amount of the position and one based on the percentage of outstanding of shares attributable to the position. With respect to the notional amount, a person would be required to file a Schedule 10B once a Security-Based Swap Position based on equity meets or exceeds $300 million, calculated on a gross basis (*i.e.,* including both long and short positions). However, the Commission also recognizes that people may attempt to evade the reporting requirements in proposed Rule 10B–1 by making efforts to keep a Security-Based Swap Position below the $300 million gross notional threshold, while also building up a position in the underlying equity securities and/or other types of non-security-based swap derivatives on such underlying security. Accordingly, proposed Rule 10B–1(b)(1)(iii)(A) would provide that once a Security-Based Swap Position exceeds a gross notional amount of $150 million, the calculation of the Security-Based Swap Position shall also include the value of all of the underlying equity securities owned by the holder of the Security-Based Swap Position (based on the most recent closing price of shares), as well as the delta-adjusted notional amount of any options, security futures, or any other derivative instruments based on the same class of equity securities.[136] The Commission believes that the proposed approach would provide greater transparency with respect to a person with significant exposure to a particular equity security, which includes a large Security-Based Swap Position, even if that position by itself would not be large enough to require the person to file a Schedule 10B.[137] In such instance, the total exposure could carry the same risks in terms of potential effects on the securities markets (including the market for security-based swaps) and to security-based swap counterparties as a Security-Based Swap Position that meets or exceeds the $300 million gross notional threshold.

Percentage Threshold

The Commission believes that including a second test that is based on the number of applicable shares represented by the Security-Based Swap Position is likely important for a number of reasons, particularly as it relates to security-based swaps based on equity securities issued by companies with a smaller market capitalization. Under those circumstances, the notional amount of such security-based swaps may not trigger either the $150 million or $300 million gross notional thresholds, and may not be likely to have a broad impact on the securities markets, but may represent a significant number of shares of the issuer and therefore carry the potential to impact the issuer.

A person would be required to file a Schedule 10B once the ''Security-Based Swap Equivalent Position'' (discussed

[133] *See supra* note 129 and accompanying text.

[134] *See infra* section VI.D.2.iii.

[135] *See supra* note 4. By contrast, CDS data has been voluntarily reported and available to the Commission for more than a decade.

[136] Proposed Rule 10B–1(b)(6) defines the term ''delta'' to mean the ratio that that is obtained by comparing (x) the change in the value of a derivative instrument to (y) the change in the value of the reference equity security. If a derivative instrument does not have a fixed delta, then generally the delta should be calculated on a daily basis, based on the most recent closing price of shares of the reference equity security. The Commission is not proposing a specific definition of ''delta-adjusted notional amount'' in order to allow for flexibility in how it is computed, but as a general matter the calculation should involve multiplying the notional amount of the derivative by the delta adjustment.

[137] The Commission recognizes, however, the limited value that would be obtained by including in the calculation equity securities held by an intermediary, such as a broker-dealer or a bank, in street name for the benefit of the person with the actual economic or beneficial ownership of such securities. Accordingly, proposed Rule 10B–1(b)(7) provides that for purposes of the $300 million gross notional threshold (and the 5% threshold discussed below), a person that is a member of a national securities exchange shall not be deemed to be the owner of any equity securities that they hold directly or indirectly on behalf of another person solely because such person is the record holder of such securities and, pursuant to the rules of such exchange, may direct the vote of such securities, without instruction, on other than contested matters or matters that may affect substantially the rights or privileges of the holders of the securities to be voted, but is otherwise precluded by the rules of such exchange from voting without instruction. Proposed Rule 10B–1(b)(7) is similar to existing Rule 13d–3(d)(2) under the Exchange Act, which provides a similar exclusion for purposes the beneficial ownership requirements in Sections 13(d) and (g) of the Exchange Act. *See* 17 CFR 240.13d–3(d)(2).

below) represents more than 5% of a class of equity securities.[138] People may attempt to evade the reporting requirements in proposed Rule 10B–1 by keeping a Security-Based Swap Equivalent Position below the threshold, while also building up a position in the underlying equity securities and/or other types of non-security-based swap derivatives on such underlying security. Accordingly, proposed Rule 10B–1(b)(1)(iii)(B) would provide that once a Security-Based Swap Equivalent Position represents more than 2.5% of a class of equity securities, the calculation of the Security-Based Swap Equivalent Position shall also include in the numerator all of the underlying equity securities owned by the holder of the Security-Based Swap Position, as well as the number of shares attributable to any options, security futures, or any other derivative instruments based on the same class of equity securities.

For purposes of this threshold, proposed Rule 10B–1(b)(2) would define the term ''Security-Based Swap Equivalent Position'' to mean the number of shares attributable to all of the security-based swaps composing a Security-Based Swap Position, as determined in accordance with proposed Rule 10B–1(b)(4). That rule defines the phrase ''number of shares attributable'' to a derivative instrument (including a security-based swap) to mean the *larger* of (in each case as applicable):

(i) The number of shares of the reference equity security that may be delivered upon on the exercise of the rights under the derivative instrument, as determined in accordance with the terms of the applicable documentation;

(ii) The number of shares of the reference equity security determined by multiplying (x) the number of shares by reference to which the amount payable under the derivative instrument is determined by (y) the delta of the applicable derivative instrument; and

(iii) The number of shares of the reference equity security determined by (x) dividing the notional amount of such derivative instrument by the most recent closing price of shares of the reference equity security, and then (y) multiplying such quotient by the delta of the applicable derivative instrument.[139]

The first prong of the definition is intended to apply primarily to physically settled instruments. Thus, if the applicable documentation refers to a specific number of shares of the reference security or provides a formula to determine the number of shares to be delivered, that number would be used for purposes of this prong. The second prong of the definition is intended to apply primarily to a cash-settled instruments that provide for a way to calculate the number of shares of the reference security based on the amount payable, with an adjustment to account for derivative instruments with a delta that is not equal to one. Finally, the third prong is intended to apply primarily to a cash-settled instrument where no such methodology exists. In that case, the number of shares attributable to the instrument would be calculated by dividing the notional amount of the instrument by the most recent closing price of the reference equity security, and multiplying the quotient by the delta of the instrument.

The above calculations would apply not only to all security-based swaps based on a single equity security, but also to security-based swaps based on a narrow-based security index containing that reference security. As an example, if a person has a Security-Based Swap Position consisting of security-based swaps on the common shares of XYZ Corporation and security-based swaps on a narrow-based security index that contains XYZ Corporation, the number of shares attributable to the index-based security-based swaps would need to be added to the number of shares attributable to the single-name security based swaps for purposes of calculating the percentage of those shares by reference to the number of outstanding shares. With respect to the index-based security-based swaps, if the documentation contained no methodology for calculating the number of shares of the reference equity security by reference to which the amount payable under the derivative instrument is determined, the third prong of proposed Rule 10B–1(b)(4) would apply. Thus, if the notional amount of security-based swaps based on the index was $100 million, and XYZ Corporation common stock constituted 40% of the index, the notional amount for these purposes would be $40 million, which would then be divided by the most recent closing price of XYZ Corporation common stock to determine the number of shares attributable to the index-based security-based swaps.[140]

3. Amendments to a Previously Filed Schedule 10B

Proposed Rule 10B–1(c) would require a person who has previously filed a Schedule 10B with the Commission to file an amendment if any material change occurs in the facts set forth in a previously filed Schedule 10B including, but not limited to, any material increase in the Security-Based Swap Positions or if a Security-Based Swap Position falls back below the applicable Reporting Threshold Amount. Any such amendment would be required to be filed on EDGAR promptly, but in no event later than the end of the first business day following the material change.

For purposes of the proposed rule, an acquisition or disposition in an amount equal to 10% or more of the position previously disclosed in Schedule 10B would be deemed ''material'' for purposes of this requirement. The Commission believes that this requirement will help ensure that regulators and market participants continue to have updated information about reportable Security-Based Swap Positions, but only so far as the updated information is material. Accordingly, proposed Rule 10B–1(c) would require a person who has previously filed a Schedule 10B to file an amendment if the amount of the Security-Based Swap Position that was previously reported increases or decreases by 10% or more. The Commission welcomes and encourages comments as to when commenters believe that an amendment should be required to be filed, any thresholds used to make such a determination, and the timeframe for making such submission.

[138] Because the definition of ''Reporting Threshold Amount'' with respect to Security-Based Swap Positions on equity securities is defined in proposed Rule 10B–1(b)(1)(iii) to mean the *lesser* of two different thresholds, one based on the notional amount of the position and one based on the percentage of outstanding shares attributable to the position, the applicable Security-Based Swap Position may have already exceeded the notional threshold. To the extent that the holder of such Security-Based Swap Position has already filed the applicable Schedule 10B with the Commission, such person would not need to file a new or amended Schedule 10B if the position subsequently exceeds the percentage threshold (or vice versa), unless an amendment to the previously-filed Schedule 10B is required pursuant to proposed Rule 10B–1(c). *See infra* section III.A.iii.

[139] Proposed Rule 10B–1(b)(4) defines the phrase ''number of shares attributable to'' for purposes of proposed Rule 10B–1(b)(2), which relates to determining the number for shares attributable to the Security-Based Swap Position when calculating the ''Security-Based Swap Equivalent Position'' and for purposes of proposed Rule 10B–1(b)(1)(iii)(B), which relates to determining the number of shares attributable to other derivatives that would be required to be added to a Security-Based Swap Equivalent Position that represents more than 2.5% of a class of equity securities.

[140] This assumes that the delta of the applicable security-based swaps was one. If not, or if the relevant instrument was one that is generally not a delta one derivative (*e.g.,* an option), the number of shares resulting from the calculation would then need to be multiplied by the delta.

B. Information Required To Be Included in Schedule 10B

Pursuant to proposed Schedule 10B, persons subject to the proposed rule would be required to report the following information:

(1) Name of reporting person (or names of reporting persons if making a joint filing as a group), whether reporting person is a member of a group and names of the members of the group if the members of the group are satisfying the group's Rule 10B–1(a)(1) filing obligation by making individual filings.

(2) Residency or place of organization of the reporting person(s).

(3) Type of reporting person(s).

(4) For reporting persons that are legal entities, the Legal Entity Identifier (''LEI'') of the reporting person, if such person has an LEI.

(5) Notional amount of the applicable Security-Based Swap Position(s) of the reporting person, along with summary information about the composition of the position as it relates to the direction (*i.e.,* long or short) and the tenor/expiration of the underlying security-based swap transactions and the product ID (such as the Unique Product Identifier, or ''UPI'') of the security-based swap(s) included in the Security-Based Swap Position, if applicable.

(6) In the case of a Security-Based Swap Position based on debt securities (including credit default swaps), ownership of: (i) All debt securities underlying a security-based swap included in the Security-Based Swap Position, including the Financial Instrument Global Identifier (''FIGI'') of each underlying debt security, if applicable, and the LEI of the issuer of each underlying debt security, if the issuer has an LEI; and (ii) all security-based swaps based on equity securities issued by the same reference entity, including the FIGI of each underlying equity security, if applicable. In addition to the FIGI, other unique security identifier(s) may be included at the filer's option.

(7) In the case of a Security-Based Swap Position based on equity securities, ownership of: (i) All equity securities underlying a security-based swap included in the Security-Based Swap Position, including the FIGI of each underlying equity security and the LEI of the issuer of each underlying equity security, if the issuer has an LEI; and (ii) all security-based swaps based on debt securities issued by the same reference entity (including credit default swaps), including the FIGI of each underlying debt security, if applicable. In addition to the FIGI, other unique security identifier(s) may be included at the filer's option.

(8) Ownership of any other instrument relating to the Security-Based Swap Position and/or any underlying security or loan or group or index of securities or loans, or any security or group or index of securities, the price, yield, value, or volatility of which, or of which any interest therein, is the basis for a material term of a security-based swap included in the Security-Based Swap Position, if not otherwise disclosed pursuant to Items 6 or 7 of this form. For any underlying security disclosed pursuant to this Item, disclose the FIGI of the security, if applicable, and the LEI of the issuer of the security, if the issuer has an LEI. In addition to the FIGI, other unique security identifier(s) may be included at the filer's option.

(9) To the extent that the Reporting Threshold Amount is based on the number of shares corresponding to a Security-Based Swap Position based on equity securities, the number of shares attributable to the Security-Based Swap Position, along with the closing price used in the calculation and the date of such closing price.

The first four items relate to the identity of the reporting person. With respect to item (3), the reference to ''type'' of reporting person would include the following categories: (i) Broker-dealer; (ii) security-based swap dealer or major security-based swap participant; (iii) bank; (iv) insurance company; (v) investment company; (vi) investment adviser; (vii) employee benefit plan or endowment fund; (viii) parent holding company/control person; (ix) savings association; (x) church plan; (xi) corporation; (xii) partnership; (xiii) individual; and (xiv) other. These categories are identical to those included in Schedule 13D, other than the addition of SBS Entities in item (ii).[141]

Items (5) through (8) require reporting of the Security-Based Swap Position, the loans or securities underlying that position, any related securities and loans, and other security-based swaps related to the applicable Security-Based Swap Position.[142] Item (9) applies only to Security-Based Swap Positions based on equity securities where the Reporting Threshold Amount is based on the number of shares corresponding to a Security-Based Swap Position and is intended to provide basic information as to how the number of shares was calculated.

At the same time, however, the Commission also understands that certain aspects of a security-based swap transaction may be sensitive or proprietary information. As previously noted, the intent of proposed Rule 10B–1 is to alert regulators and the market, including counterparties to security-based swap trades and the companies whose securities underlie security-based swaps, that one or more market participants are amassing a large position in security-based swaps. The items listed above are intended to achieve that objective without requiring market participants to publicly disclose sensitive or proprietary information about their Security-Based Swap Positions. In particular, Schedule 10B does not require reporting persons to disclose any information about their counterparties, including their identities, to any security-based swap or other related derivatives; only the aggregated positions would need to be disclosed. Moreover, Schedule 10B only requires reporting persons to include a ''brief description'' of any contracts, arrangements, understandings or relationships with respect to any security-based swaps included in the Security-Based Swap Position or any underlying or related securities (including security-based swaps) or loans required to be disclosed pursuant the form; the agreements themselves would not need to be disclosed. The Commission believes that structuring Schedule 10B in such a manner would help to alleviate concerns regarding the potential public disclosure of sensitive or proprietary information, and we encourage commenters to provide information as to whether the Commission should take any additional measures to accomplish that goal, consistent with the underlying objectives of proposed Rule 10B–1.

Finally, proposed Rule 10B–1(e) would provide that if some or all of the information required to be disclosed on proposed Schedule 10B is publicly available on EDGAR at the time the Schedule 10B is required to be filed, such information may be incorporated by reference in answer, or partial answer, to any item of Schedule 10B. This provision is intended to make the proposed rule more efficient in cases where any required information is publicly available on EDGAR. In such cases, the Schedule 10B need only cite to the filing where the information can be found.[143]

[141] *See* 17 CFR 240.13d–101.

[142] As previously explained, for purposes of the definition of ''Security-Based Swap Position,'' security-based swaps based on equity securities issued by a reference entity would constitute a separate Security-Based Swap Position as compared to security-based swaps based on debt securities of the same reference entity. *See supra* note 125 and accompanying text. As a result, if a reporting party had a Security-Based Swap Position composed of security-based swaps based on equity securities and separate security-based swaps based on debt securities of the same issuer, the Security-Based Position would be disclosed pursuant to Item (5), and the debt security-based swaps would be disclosed pursuant to Item (6). In the reverse scenario, a Security-Based Position composed of security-based swaps based on debt securities would be disclosed pursuant to Item (5), and the equity security-based swaps would be disclosed pursuant to Item (7). Item (8) would include any other instrument relating to the Security-Based Swap Position and/or any underlying security or loan or group or index of securities or loans.

[143] The Commission has previously allowed people subject to reporting and other disclosure obligations to incorporate certain information by reference into those filings. *See e.g.,* Rule 12b–23 under the Exchange Act, which establishes requirements for incorporating information by

Continued

C. Cross-Border Issues

As the Commission has stated in prior releases, security-based swap transactions currently take place across national borders, with agreements negotiated and executed between counterparties in different jurisdictions (which might then be booked and risk-managed in still other jurisdictions).[144] Given the global nature of the security-based swap market, an effective application of proposed Rule 10B–1 necessitates identifying which transactions in this global market will be subject to these reporting requirements.

To achieve that objective, proposed Rule 10B–1(d) would provide that the reporting requirements of the rule would apply to all Security-Based Swap Positions so long as: (1) Any of the transactions that compose the Security-Based Swap Position would be required to be reported pursuant to 17 CFR 242.908 (''Rule 908'') of Regulation SBSR; [145] or (2) the reporting person holds any amount of reference securities underlying the Security-Based Swap Position (or would be deemed to be the beneficial owner of such reference securities, pursuant to Section 13(d) of the Exchange Act and the rules and regulations thereunder) and: (i) The issuer of such reference security is a partnership, corporation, trust, investment vehicle, or other legal person organized, incorporated, or established under the laws of the U.S. or having its principal place of business in the U.S.; or (ii) such reference security is part of a class of securities registered under Section 12 or 15(d) of the Exchange Act.[146]

Rule 908(a) provides that a security-based swap is subject to regulatory reporting and public dissemination if: (i) There is a direct or indirect counterparty that is a U.S. person on either or both sides of the transaction; or (ii) the security-based swap is accepted for clearing by a clearing agency having its principal place of business in the United States.[147] The rule also provides that a security-based swap that is not included in the above provisions is subject to regulatory reporting but not public dissemination if there is a direct or indirect counterparty on either or both sides of the transaction that is a registered security-based swap dealer or a registered major security-based swap participant.[148]

The Commission believes that tying the reporting requirements in proposed Rule 10B–1 to the regulatory reporting and public dissemination requirements in Regulation SBSR is appropriate for similar reasons set forth when Rule 908 was adopted. Specifically, the Commission at the time explained that when a U.S. person enters into a security-based swap, the security-based swap necessarily exists at least in part within the United States, such that requiring regulatory reporting and requiring public dissemination would be consistent with the Commission's territorial approach in a number of areas, including the application of Title VII requirements.[149]

In addition to tying the reporting requirement in proposed Rule 10B–1 to regulatory reporting and public dissemination, the proposed rule also would apply when the reporting person holds any amount of reference securities underlying the Security-Based Swap Position (or would be deemed to be the beneficial owners of such reference securities, pursuant to Section 13(d) of the Exchange Act and the rules and regulations thereunder) and: (i) The issuer of such reference security is a partnership, corporation, trust, investment vehicle, or other legal person organized, incorporated, or established under the laws of the U.S. or having its principal place of business in the U.S.; or (ii) such reference security is part of a class of securities registered under Section 12 or 15(d) of the Exchange Act.[150] As explained above, the Commission has previously applied a territorial approach to the application of Title VII—including the requirements relating to regulatory reporting and public dissemination of security-based swap transactions—that is grounded in the text of the relevant statutory provisions and is designed to help ensure that the Commission's application of the relevant provisions is consistent with the goals that the statute was intended to achieve.[151] Under this approach, the first step is to identify the congressional focus of the statutory provision. If the activity that is the focus of the statutory provision occurs here, then application of the statutory provision to that activity is a permissible domestic application of the statute. When the statutory text provides for further Commission interpretation of statutory terms or requirements, this analysis may require the Commission to identify through rulemaking or other regulatory action, a reasonable understanding (which may look to prior interpretations of the relevant statutory text) the specific activity that is relevant under the statute.[152]

Section 10B generally provides the Commission with authority to require any person effecting transactions for such person's own account or the account of others in any security-based swap and any underlying security or loan or group or index of securities or loans (as well as any related securities) to report such information as the Commission may prescribe regarding any position or positions in any security-based swap and any underlying or related securities, loans, or indexes.[153] In considering this statutory text, the Commission understands that a congressional focus of Section 10B to be the promotion of transparency through disclosure within the U.S. securities markets of security-based swap positions that (at least in part) occur in the United States or other security-based swap transactions that involve persons who have positions in U.S. issuers or U.S. registrants. This congressional focus is reasonably understood to include U.S. security-based swaps that are at least partially within the U.S.

reference into any Commission registration statement or report filed pursuant to Sections 12(b) and 12(g), 13 or 15(d) of the Exchange Act. 17 CFR 240.12b–21 and 12b–23. Consistent with Exchange Act Rule 12b–23, information cannot be incorporated by reference if such incorporation would make the disclosure incomplete, unclear, or confusing.

[144] *See* Cross-Border Security-Based Swap Activities; Re-Proposal of Regulation SBSR and Certain Rules and Forms Relating to the Registration of Security-Based Swap Dealers and Major Security-Based Swap Participants, Exchange Act Release No. 69490 (May 1, 2013), 78 FR 30968, 30976 n. 48 and accompanying text (May 23, 2013).

[145] *See* 17 CFR 242.908.

[146] *See* proposed Rule 10B–1(d).

[147] *See* 17 CFR 242.908(a). Rule 908 defines ''U.S. person'' by cross-referencing to 17 CFR 240.3a71–3(a)(4) (''Rule 3a71–3(a)(4)'') of the Exchange Act, which provides that, subject to certain exceptions, a ''U.S. person'' means any person that is: (i) A natural person resident in the United States; (ii) a partnership, corporation, trust, investment vehicle, or other legal person organized, incorporated, or established under the laws of the United States or having its principal place of business in the United States; (iii) an account (whether discretionary or non-discretionary) of a U.S. person; or (iv) an estate of a decedent who was a resident of the United States at the time of death. *See* 17 CFR 240.3a71–3(a)(4).

[148] *See* 17 CFR 242.908(a).

[149] *See* 2015 Regulation SBSR Adopting Release, 80 FR at 14649–14650.

[150] *See* proposed Rule 10B–1(d).

[151] *See* 2015 Regulation SBSR Adopting Release, 80 FR at 14649–14650, n. 790 (citing *Morrison* v. *Nat'l Australia Bank, Ltd.,* 130 S. Ct. 2869, 2884 (2010) (explaining that in order to determine whether a particular application of a statutory provision is a domestic application of that provision, it is necessary to identify the congressional focus of the statutory provision and then determine whether the subject the congressional focus is in the United States or overseas)).

[152] *See* 2015 Regulation SBSR Adopting Release, 80 FR at 14649–14650, n. 791 and accompanying text.

[153] *See* 15 U.S.C. 78j–2.

securities markets or any other securities that trade within the U.S. securities markets where at least one party has an ownership interest in any of the underlying or related U.S. securities or loans. This understanding of the congressional focus is based in part on the fact that paragraph (a) of Section 10B applies to the Commission's authority to establish position limits in security-based swaps (on which the Commission has not yet acted), and paragraph (d), which is titled ''Large Trader Reporting'' applies to the Commission's authority to promulgate rules regarding reporting of positions in security-based swaps.[154]

The proposed rule would apply when the reporting person holds any amount of reference securities underlying the Security-Based Swap Position (or would be deemed to be the beneficial owner of such reference securities, pursuant to Section 13(d) of the Exchange Act and the rules and regulations thereunder), so long as one of two conditions are satisfied.[155] In particular, such underlying securities or loans must either be: (1) Issued by an entity subject to U.S. jurisdiction (*i.e.,* such issuer is either a partnership, corporation, trust, investment vehicle, or other legal person organized, incorporated, or established under the laws of the U.S. or having its principal place of business in the U.S.) or (2) subject to ongoing reporting obligations under the Federal securities laws (*i.e.,* Section 12 or 15(d) of the Exchange Act).[156]

[154] *See id.* Paragraph (d) of Section 10B provides the Commission with authority to require reporting of positions by any person that ''effects transactions for such person's own account or the account of others.'' That provision incorporates paragraph (a) to define the scope of the security-based swaps and other related securities that would be subject to the reporting requirement. Notably, paragraphs (a)(1) and (2) of Section 10B focus on the Commission's authority to establish position limits in security-based swaps and related securities as necessary and appropriate in the public interest or for the protection of investors, does not focus on where the transactions underlying those positions were ''effected.''

[155] In particular, Rule 13d–3 under the Exchange Act, which was adopted pursuant to Section 13(d), establishes the standards for determining when a person is the beneficial owner of a relevant security. Among other things, that rule provides that for the purposes of Sections 13(d) and 13(g), a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (1) Voting power which includes the power to vote, or to direct the voting of, such security; and/or, (2) investment power which includes the power to dispose, or to direct the disposition of, such security. *See* 17 CFR 240.13d–3(a).

[156] *See* 15 U.S.C. 78l or 78o(d).

D. Structured Data Requirement for Schedule 10B

To facilitate analysis of the reports submitted on Schedule 10B via EDGAR, the Commission is proposing to require filers to submit Schedule 10B using a structured, machine-readable data language. In particular, the Commission is proposing that Schedule 10B be structured using Financial Information eXchange Markup Language (''FIXML''), a structured data language built on the open Financial Information eXchange (''FIX'') standard used by market participants to communicate information about securities transactions and markets to each other.[157]

The Commission believes a FIXML requirement for Schedule 10B will further the goal of increasing transparency in the security-based swaps market. Because the reports on Schedule 10B would be publicly available in a machine-readable data language, the information disclosed by filing persons would be much more readily accessible and usable for extraction, filtering, comparison, threshold notification, and other analyses on a large scale by the public and the Commission.

To allow for flexibility in complying with this requirement, the Commission would provide filing persons with a fillable web form that would convert inputted reports into FIXML, allowing filers to, at their option, either submit Schedule 10B directly in FIXML, or use the fillable web form to generate the Schedule 10B in FIXML.[158] In addition, the Commission would develop electronic ''style sheets'' that, when applied to the reported FIXML data on Schedule 10B, would represent that data in human-readable form.

E. Request for Comment

The Commission generally requests comments on all aspects of proposed Rule 10B–1. In addition, the Commission requests comments on the following specific issues:

- Should the Commission utilize its authority under Section 10B(d) of the Exchange Act to require public reporting of certain Security-Based Swap Positions, any security or loan or group or index of securities or loans underlying the Security-Based Swap Position, and any other instrument relating to such security or loan or group or index of securities or loans? Why or why not?
- Do commenters agree with the requirement that the Schedule 10B be filed promptly, but in any event no later than the end of the first business day following the day of execution of the security-based swap transaction that results in the Security-Based Swap Position first exceeding the Reporting Threshold Amount? Does that timing allow for sufficient time to perform the calculations necessary to determine whether a Schedule 10B must be filed or amended and to ensure that the form contains all of the required information? Why or why not? If commenters disagree with the proposed timing, what alternative timeframe should be used for purposes of the proposed rule and why?
- Do commenters agree with the scope of the definition of ''Security-Based Swap Position,'' which determines which security-based swaps should be aggregated for purposes of determining when reporting is required and the security-based swaps that must be disclosed? Why or why not? Should this definition be amended in any way? If so, how should the definition be modified and why?
- Should the definition of ''Security-Based Swap Position'' aggregate only security-based swaps of the same type (*i.e.,* security-based swaps based on equity securities *or* security-based swaps based on debt (including CDS)) and the same underlying security or reference entity? Why or why not? If not, should a Security-Based Swap Position include all security-based swaps based on the same underlying security or reference entity, regardless of whether they are debt (including CDS) or equity-based? Similarly, should a Security-Based Swap Position include all security-based swaps on the same underlying security or reference entity, as well as similar or related securities or reference entities? If so, how should the proposed rule define what is ''similar'' for these purposes?
- Should proposed Rule 10B–1 require reporting of large positions in security-based swaps, regardless of the underlying reference entity, security, loan, or group or index of securities or loans that a person has with all their counterparties, as a means of identifying persons with positions large enough to have a material impact on the securities markets in general? Why or why not? For example, 17 CFR 240.13h–1 (''Rule 13h–1'') requires traders who engage in a substantial level of trading activity to identify themselves to the Commission by filing a Form 13H with the Commission. Pursuant to Rule 13h–1, a ''large trader'' includes a person whose transactions in exchange-listed securities equal or exceed two million shares or $20 million during any calendar day, or 20 million shares or $200 million during any calendar month. Those thresholds are calculated based on the trader's entire position in all NMS securities, as opposed to its positions in the securities of the same

[157] FIXML and the underlying FIX communications protocol is maintained by the FIX Trading Community, a not-for-profit industry-driven standards-setting body. Current FIXML uses include derivatives post-trade clearing, settlement, and reporting. More information about FIXML and the FIX Trading Community is available at the ''FIXML'' and ''FIX Trading Community'' web pages on the FIX Trading website (*available at: https://www.fixtrading.org/standards/fixml/* and *https://www.fixtrading.org/overview/*).

[158] *See* EDGAR Filer Manual (Volume II) version 59 (September 2021), Chapter 8 (discussing the preparation and transmission of online submissions to the EDGAR system).

issuer. Should the Commission consider adopting a similar requirement for positions in security-based swaps? Why or why not?

- Should proposed Rule 10B–1 require that persons subject to the reporting requirement of the rule submit Schedule 10B on EDGAR? Why or why not? Should the rule require or permit a different means of submitting Schedule 10B, either in lieu of, or in addition to, EDGAR? If so, how should the form be submitted and why? Also, how would such additional or substitute means of submission satisfy the objective of Rule 10B–1 to make the information included in Schedule 10B publicly available?
- Should the Commission require Schedule 10B to be submitted in a structured data language? Why or why not? If so, is the proposed FIXML data language the most appropriate structured data language to use for Schedule 10B, or would another structured data language be more appropriate? If the latter, please specify the structured data language that would be more appropriate for Schedule 10B, and explain why.
- Do commenters agree with the proposed definition of ''Reporting Threshold Amount'' in the context of CDS? Why or why not? Is basing the reporting requirement in proposed Rule 10B–1 on the notional amount of CDS positions appropriate? Why or why not? Is there a better method for triggering the requirement? If so, what method should be used and why? Are the proposed $150 million long, $150 million short, and $300 million gross notional thresholds for CDS positions appropriate? Why or why not? Should the Commission further specify which debt securities would be permitted to be netted against the aggregate long CDS position? Should additional types of netting be permitted, such as by allowing additional types of securities to be netted against the aggregate CDS position or by allowing long and short CDS transactions to net against each other? Should the rule permit people to net their short positions in deliverable bonds against their short CDS positions? Why or why not? To the extent that commenters believe that additional netting should be permitted, please provide as much detail as possible as to any limitations in scope or amount that should be included in the calculation and why such limitations should be included?
- Do commenters agree with the proposed definition of ''Reporting Threshold Amount'' in the context of security-based swaps on debt securities that are not CDS? Why or why not? Is basing the reporting requirement in proposed Rule 10B–1 on the notional amount of the position appropriate? Why or why not? Is there a better method for triggering the requirement? If so, what method should be used and why? Is the proposed threshold of $300 million on a gross notional basis appropriate? Why or why not? Should proposed Rule 10B–1 allow for netting when calculating the Security-Based Swap Position on debt security-based swaps, such as by allowing any underlying or related debt securities to be netted against the aggregate position or by allowing long and short security-based swap transactions to net against each other? To the extent that commenters believe that netting should be permitted, please provide as much detail as possible as to any limitations in scope or amount that should be included in the calculation and why such limitations should be included.
- Should the proposed definition of ''Reporting Threshold Amount'' in the context of either CDS or security-based swaps based on debt securities that are not CDS (or both) also include a percentage threshold, similar to what the Commission proposed in the context of security-based swaps based equity securities, in order to account for smaller issuers of debt? Why or why not? If commenters believe that such an approach would be useful for CDS, should the threshold be based on the outstanding number of potentially deliverable obligations or the outstanding amount of CDS? Commenters are encouraged to be as specific as possible in explaining how such a test would work.
- Do commenters agree with the proposed definition of ''Reporting Threshold Amount'' in the context of security-based swaps on equity securities, including having both a threshold based on the notional amount of the Security-Based Swap Position and a threshold based on the number of shares attributable to the Security-Based Swap Position? Why or why not? Do commenters agree with the proposed $300 million and 5% thresholds? If not, how should they be modified? Should the Commission require people to include all related securities in the calculation of their Security-Based Swap Positions once they exceed an intermediate threshold in order to prevent evasion? If commenters agree with this approach, are $150 million and 2.5% appropriate thresholds to use for these purposes? Why or why not?
- Should the Commission consider a different methodology for purposes of the definition of ''Reporting Threshold Amount'' in the context of security-based swaps on equity securities? For example, should proposed Rule 10B–1 include a threshold based on number of shares represented by the Security-Based Swap Position as a percentage of the average daily trading volume of those shares, as measured by the number of shares traded and calculated over a fixed period (*e.g.,* the preceding six months)?
- Do commenters agree with the proposed requirements regarding the submission of amendments to Schedule 10B, as set forth in proposed Rule 10B–1(c), including the 10% threshold for increases or decreases of the Security-Based Swap Position? Why or why not? If not, what should be modified and why?
- Do commenters agree with information the Commission is proposing to be required to be disclosed on Schedule 10B? Why or why not? Should other information be required? If so, what information should be added and why? Should information currently proposed to be included not be required? If so, what information should be deleted from the proposed schedule and why?
- Do commenters agree with the Commission's proposal not to require reporting of a reporting party's counterparties? Why or why not? How much does the absence of counterparty information impact the usefulness of the reporting? Is there any other information that should not be required to be disclosed on Schedule 10B due to it being sensitive or proprietary in nature? If so, what information should not be disclosed and why?
- In cases where a Schedule 10B filing is made for a group of persons, should the Commission require any additional information about the group, such as a brief description of any contracts, arrangements, understandings or relationships among the persons in the group, as set forth in Item (10) of proposed Schedule 10B? Why or why not? What other information should be included?
- Do commenters agree with the form and scope of proposed Rule 10B–1(d), which would identify when the reporting requirements of the rule would apply to all Security-Based Swap Positions, including in the context of cross-border security-based swap transactions? Why or why not? Are there any changes to the proposal that the Commission should make to modify the scope of the positions that would be subject to the rule? If so, what changes should be made and why?
- Proposed Rule 10B–1(e) would provide that if some or all of the information required to be disclosed on proposed Schedule 10B is publicly available on EDGAR at the time the Schedule 10B is required to be filed, such information may be incorporated by reference in answer, or partial answer, to any item of Schedule 10B. Should the Commission allow reporting persons to incorporate information by reference in proposed Schedule 10B? Why or why not? Should proposed Rule 10B–1(e) be modified in any way? If so, how? Are there any aspects of this proposal that should be modified or added to help make the filing requirement under proposed Schedule 10B more efficient? If so, which ones and why? If the Commission were to adopt this provision, do commenters anticipate that large portions of these filings would be incorporated by reference? If so, what burdens, if any, could this provision create for persons utilizing the data reported in the schedule?

IV. General Request for Comment

We request and encourage any interested person to submit comments regarding the proposed rules, specific issues discussed in this release, and other matters that may have an effect on the proposed rules. With regard to any comments, we note that such comments are of particular assistance to our rulemaking initiative if accompanied by supporting data and analysis of the issues addressed in those comments.

V. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'') [159] imposes certain requirements on Federal agencies in connection with the conducting or sponsoring of any ''collection of

[159] 44 U.S.C. 3501 *et seq.*

information.'' [160] For example, 44 U.S.C. 3507(a)(1)(D) provides that before adopting (or revising) a collection of information requirement, an agency must, among other things, publish a notice in the **Federal Register** stating that the agency has submitted the proposed collection of information to the Office of Management and Budget (''OMB'') and setting forth certain required information, including: (1) A title for the collection information; (2) a summary of the collected information; (3) a brief description of the need for the information and the proposed use of the information; (4) a description of the likely respondents and proposed frequency of response to the collection of information; (5) an estimate of the paperwork burden that shall result from the collection of information; and (6) notice that comments may be submitted to the agency and director of OMB.[161]

Certain provisions of the proposed rules contain ''collection of information'' requirements within the meaning of the PRA. The Commission is submitting these collections of information to OMB for review in accordance with 44 U.S.C. 3507 and 5 CFR 1320.11. 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 control number.

Specifically, proposed Rule 10B–1 (including Schedule 10B) would impose new collection of information requirements.[162] The title of the new collections of information is ''Schedule 10B—Reporting of Security-Based Swap Positions.'' OMB has not yet assigned a control number to this new collection of information. The Commission is not proposing to amend the collection of information entitled ''Form ID'' (OMB Control No. 3235–0328).[163]

A. Summary of Collections of Information

Proposed Rule 10B–1(a)(1) would require any person (and any entity controlling, controlled by or under common control with such person), or group of persons, who through any contract, arrangement, understanding or relationship, after acquiring or selling directly or indirectly, any security-based swap, is directly or indirectly the owner or seller of a Security-Based Swap Position [164] that exceeds the Reporting Threshold Amount, [165] shall file with the Commission a statement containing the information required by Schedule 10B using EDGAR in FIXML. Pursuant to proposed Rule 10B–1(a)(2), each person subject to the rule would be required to file its Schedule 10B promptly, but in no event later than the end of the first business day following the day of execution of the security-based swap transaction that results in the Security-Based Swap Position first exceeding the Reporting Threshold Amount.

Proposed Rule 10B–1(c) would require a person who has previously filed a Schedule 10B with the Commission to file an amendment if any material change occurs in the facts set forth in a previously filed Schedule 10B including, but not limited to, any material increase in the Security-Based Swap Positions or if a Security-Based Swap Position falls back below the applicable Reporting Threshold Amount. Any such amendment would be required to be filed on EDGAR promptly, but in no event later than the end of the first business day following the material change. Moreover, for purposes of the proposed rule, an acquisition in an amount equal to 10% or more of the position previously disclosed in Schedule 10B would be deemed ''material'' for purposes of this requirement.

Pursuant to proposed Schedule 10B, persons subject to proposed Rule 10B–1 would generally be required to report, among other things, certain information about their Security-Based Swap Positions, as well as positions in any security or loan underlying the Security-Based Swap Position, and positions in any other instrument relating to the underlying security or loan or group or index of securities or loans.[166] Schedule 10B also generally requires information regarding the identity and type of the applicable reporting person or group of persons.[167]

B. Proposed Use of Information

The Commission believes that the information required to be disclosed on Schedule 10B will be used as follows: (1) To provide market participants (including counterparties, issuers and their stakeholders) and regulators with access to information that may indicate that a person (or a group of persons) is building up a large security-based swap position, which in some cases could be indicative of potentially fraudulent or manipulative purposes; (2) to alert market participants and regulators to the existence of concentrated exposures to a limited number of counterparties, which should inform those market participants

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[160] *See* 44 U.S.C. 3502(3).

[161] *See* 44 U.S.C. 3507(a)(1)(D); *see also* 5 CFR 1320.5(a)(1)(iv).

[162] The Commission does not believe that re-proposed Rule 9j–h1 or proposed Rule 15Fh–4(c) contain a collection of information requirement within the meaning of the PRA. Specifically, re-proposed Rule 9j–1 contains prohibitions designed to prevent fraud, manipulation, and deception in connection with effecting transactions in, or inducing or attempting to induce the purchase or sale of, any security-based swap. Proposed Rule 15Fh–4(c) would generally make it unlawful for certain specified persons to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence an SBS Entity's CCO in the performance of their duties under the federal securities laws or the rules and regulations thereunder. Neither of those rules require a person to establish, maintain, and enforce written policies and procedures reasonably designed to ensure compliance with the applicable rule. However, to the extent that a person is already subject to a similar policies and procedures requirement, any updates to those policies and procedures would likely be captured by an existing collection of information. For example, as previously explained, Rule 15Fh–3(h) requires an SBS Entity to establish and maintain a system to supervise its business and the activities of its associated persons and that system must be reasonably designed to prevent violations of the provisions of applicable federal securities laws and the rules and regulations thereunder. In the PRA analysis when that rule was adopted, the Commission estimated that each SBS Entity would spend 60 hours per year to update each of the policies and procedures required by Rule 15Fh–3. *See* Business Conduct Standards Adopting Release, 81 FR at 30094. Given that both re-proposed Rule 9j–1 and proposed Rule 15Fh–4(c) are intended solely to identify actions that an SBS Entity is not permitted to take, and as such do not make substantive modifications to any existing collection of information or impose new information collection requirements within the meaning of the PRA. Accordingly, we are not revising any burden and cost estimates in connection with these amendments.

[163] To the extent that a person subject to a reporting requirement pursuant to proposed Rule 10B–1 has not previously made at least one filing with the Commission via EDGAR, such person would need to file a Form ID with the Commission in order to gain access to EDGAR. Form ID is used to request the assignment of access codes to file on EDGAR. Upon successfully filing a Form ID, a person will be provided with, among other things, a given a Central Index Key (''CIK'') number that uniquely identifies each filer. Given that the thresholds in proposed Rule 10B–1 are set at a level that will likely only capture persons previously subject to an EDGAR filing requirement (such as, among others, SBS Entities, large traders, broker-dealers, or Exchange Act reporting companies), the Commission estimates that most, if not all, persons required to submit a Schedule 10B will already have a CIK and the ability to access EDGAR. Thus, the Commission believes that the proposed rules would not impose substantive new burdens on the overall population of respondents or affect the current overall cost estimates for Form ID. Therefore, we believe that the current burden and cost estimates for Form ID remain appropriate. Accordingly, we are not revising the current burden or cost estimates for Form ID.

[164] *See supra* notes 120–121 and accompanying text (describing proposed Rule 10B–1(b)(3), which defines the term ''Security-Based Swap Position'').

[165] Proposed Rule 10B–1 would include specific quantitative thresholds for when reporting would be required. *See supra* sections III.A.1 (defining ''Reporting Threshold Amount'' for purposes of Security-Based Swap Positions consisting of CDS and other security-based swaps based on debt securities) and III.A.2 (defining ''Reporting Threshold Amount'' for purposes of Security-Based Swap Positions consisting of security-based swaps based on equity securities).

[166] *See supra* section III.B.

[167] *See id.*

and regulators of the attendant risks, allow counterparties to risk manage and lead to better pricing of the security-based swaps (as a result of all market participants having access to the information about the positions), and (3) in the case of manufactured or other opportunistic strategies in the CDS market, to provide market participants and regulators with advance notice that a person (or a group of persons) is building up a large CDS position with an incentive to vote against their interests as a debt holder, possibly with an intent to harm the company, even if such conduct is not inherently fraudulent.

C. Respondents

Based on the information in Figure 6 in section VI.D.2.iii.(A) (Economic Analysis), the Commission believes that up to 400 persons will be required to file at least one Schedule 10B with the Commission with respect to Security-Based Swap Positions consisting of CDS annually. Because reporting transaction data regarding other types of security-based swaps has only recently become mandatory, the Commission does not yet have a precise estimate as to the number of persons we would expect to file reports with respect to Security-Based Swap Positions consisting of security-based swaps based on equity securities and other debt securities (non-CDS).

However, in describing the security-based swap market as a whole, the Commission has previously stated that it believes that single-name CDS contracts make up a majority of that market.[168] Thus, the Commission expects that the number of persons that would submit reports with respect to Security-Based Swap Positions consisting of security-based swaps based on equity securities and other debt securities should not exceed the 400 persons we expect to submit reports related to CDS positions annually. Although the Commission recognizes that there is likely to a considerable number of people who will have both equity- and debt-based Security Based Swap Positions that will be required to be reported, to be conservative, the Commission is doubling the estimate; we estimate the total number of persons who will be subject to the proposed rule. Accordingly, the Commission estimates that 800 respondents will be subject to at least one reporting requirement pursuant to proposed Rule 10B–1 annually.

At the same time, however, the Commission also understands that some number of persons may have Security-Based Swap Positions that, while not large enough to trigger a reporting requirement under proposed Rule 10B–1, will be close enough to the threshold to warrant active monitoring of those positions. Accordingly, the Commission estimates that 850 respondents will likely need to develop a technological infrastructure to monitor their Security-Based Swap Positions, which includes the 800 respondents estimated to be subject to a reporting requirement pursuant to proposed Rule 10B–1 and an additional 50 respondents whose positions may not ever trigger a reporting requirement.

D. Total Annual Recordkeeping Burden

1. Initial Costs and Burdens

As discussed above, the Commission believes that up to 850 respondents will likely need to develop a technological infrastructure to calculate and monitor their Security-Based Swap Positions, even if some of those entities do not have at least one Security-Based Swap Position that is required to be reported pursuant to proposed Rule 10B–1(a). The Commission believes that most, if not all, persons who are likely to have Security-Based Swap Positions large enough to trigger the reporting thresholds will have the resources to develop and implement this technological infrastructure using internal personnel and resources. The Commission also believes that each respondent will incur a one-time initial internal burden of approximately 355 hours (or $101,740) per respondent to develop such technological infrastructure, which amounts to 301,750 hours (or $86,479,000) in the aggregate for all 850 respondents.[169] These estimates are similar to the estimates the Commission used in connection with Regulation SBSR.[170] Although the Commission recognizes that the system referred to in the Regulation SBSR Adopting Release involved capturing security-based swap transaction data, whereas the requirement in proposed Rule 10B–1 relates to aggregated security-based swap positions (as well as related securities that are not security-based swaps), we also believe that the costs of each system, regardless of whether it collects transaction or position data are sufficiently similar.

Because many of these 850 respondents may also be reporting parties pursuant to Regulation SBSR, it is possible that such persons may be able to leverage some of the technology used in connection with the transaction reporting system to build the system necessary to comply with proposed Rule 10B–1. Nevertheless, the Commission believes it appropriate to use the more conservative estimate in this proposing release given that the Commission has not previously proposed or adopted position reporting requirements with respect to security-based swaps.

2. Ongoing Costs and Burdens

In addition to developing the technological infrastructure to calculate and monitor their Security-Based Swap Positions in order to comply with the requirements of proposed Rule 10B–1, each respondent will be required to maintain and operate such system on an ongoing basis. As before, the Commission believes that the persons who are likely to be subject to the rule will likely have the personnel and resources to maintain these systems internally. As such, the Commission estimates that reach respondent will incur an annual internal burden of 436 hours (or $77,000), which amounts to 370,600 hours (or $65,450,000) in the aggregate for all 850 respondents.[171]

In addition to maintaining and operating such technological infrastructure, the Commission also believes that each respondent will incur a $1,000 annual internal cost for the technology necessary to store such security-based swap position data, or $850,000 in the aggregate for all 850 respondents.[172] As before, these estimates are similar to the estimates the

[168] *See* Risk Mitigation Adopting Release, 85 FR at 6391–92.

[169] This estimate is based on the following internal costs: [(Sr. Programmer (160 hours) at $303 per hour) + (Sr. Systems Analyst (160 hours) at $260 per hour) + (Compliance Manager (10 hours) at $283 per hour) + (Director of Compliance (5 hours) at $446 per hour) + (Compliance Attorney (20 hours) at $334 per hour)] = $101,740 per respondent × 850 respondents = $86,479,000. All hourly cost figures are based upon data from SIFMA's Management & Professional Earnings in the Securities Industry 2013 (modified by the SEC staff to account for an 1800-hour-work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead).

[170] *See* 2015 Regulation SBSR Adopting Release, 80 FR at 14701 n. 1232. Specifically, the Commission estimated the burden of building an internal order and trade management system capable of capturing the relevant transaction information.

[171] This estimate is based on the following internal costs: [(Sr. Programmer (32 hours) at $303 per hour) + (Sr. Systems Analyst (32 hours) at $260 per hour) + (Compliance Manager (60 hours) at $283 per hour) + (Compliance Clerk (240 hours) at $64 per hour) + (Director of Compliance (24 hours) at $446 per hour) + (Compliance Attorney (48 hours) at $334 per hour)] = $77,092 per respondent × 850 respondents = $65,450,000.

[172] This estimate is based on the following internal: [($250/gigabyte of storage capacity) × (4 gigabytes of storage)] = $1,000 × 850 respondents = $850,000.

Commission used in connection with Regulation SBSR.[173] Also consistent with the calculation of the initial burdens, the Commission believes it appropriate to use the more conservative estimate in this proposing release (*i.e.,* without regard to the possibility of leveraging some parts of the Regulations SBSR transaction reporting systems) given that the Commission has not previously proposed or adopted position reporting requirements with respect to security-based swaps.

Finally, the collection of information includes the filings required to be reported to the Commission pursuant to Rule 10B–1. The Commission believes that persons that exceed the reporting thresholds in proposed Rule 10B–1(b)(1) will submit an estimated 1,000 reports per week. This number is based on information in section VI.D.2.iii.(A) (Economic Analysis), which estimates that the Commission will receive approximately 362 reports related to Security-Based Swap Positions that are CDS from U.S. persons, and 291 reports related to Security-Based Swap Positions that are CDS from non-U.S. persons.[174] However, given that such range may be overestimating the number of reports on both ends of that spectrum, as discussed in section VI.D.2.iii.(A), the Commission believes it reasonable to use an aggregate number of approximately 500 reports per week.

In addition, because the Commission does not yet have the data necessary to make a similar estimate for security-based swaps based on equity securities or other debt securities, we are doubling the estimate provided for CDS positions, for a total of 1,000 reports per week. As explained in connection with estimating the number of respondents that will be required to submit reports pertaining to CDS positions, we believe that doubling the estimate related to CDS positions is reasonable given what we know about the composition of the security-based swap market.[175] Accordingly, the Commission believes that it will receive 52,000 reports annually.[176]

The Commission also estimates that each of those estimated 52,000 reports will take approximately 14.5 hours to complete. This number is consistent with the estimate used in the collection of information for Schedule 13D.[177] Although the Commission recognizes that proposed Rule 10B–1 and Regulation 13D–G differ in terms of both purpose and scope, we believe that the process of completing both forms would be similar. Accordingly, the Commission estimates that all respondents will incur an annual burden of 754,000 hours in the aggregate to complete these 52,000 reports on proposed Schedule 10B.

E. Collection of Information Is Mandatory

The collection of information for proposed Rule 10B–1 (including Schedule 10B) is a mandatory collection of information.

F. Confidentiality

Given the intended benefits of public reporting of the information required to be reported on Schedule 10B pursuant to proposed Rule 10B–1, as set forth in section I.C and reiterated in section V.B., responses made pursuant to this collection of information would not be confidential and would be publicly available.

G. Request for Comment

We request comment on whether our estimates are reasonable. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (4) determine whether there are ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology. Persons wishing to submit comments on the collection of information requirements of the proposed amendments should direct them to the OMB Desk Officer for the Securities and Exchange Commission, *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov,* and should send a copy to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090, with reference to File No. S7–32–10. OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication of this release; therefore a comment to OMB is best assured of having its full effect if OMB receives it within 30 days after publication of this release. Requests for materials submitted to OMB by the Commission with regard to these collections of information should be in writing, refer to File No. S7–32–10, and be submitted to the Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

VI. Economic Analysis

A. Introduction

The Commission is mindful of the economic effects, including the costs and benefits, of re-proposed Rule 9j–1, proposed Rule 10B–1, and proposed Rule 15Fh–4(c). Section 3(f) of the Exchange Act requires the Commission, whenever it engages in rulemaking pursuant to the Exchange Act and is required to consider or determine whether an action is necessary or appropriate in the public interest, also to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.[178] In addition, Section 23(a)(2) of the Exchange Act requires the Commission, when making rules under the Exchange Act, to consider the impact the proposed rules would have on competition.[179] Section 23(a)(2) of the Exchange Act also provides that the Commission shall not adopt any rule that would impose a

[173] *See* 2015 Regulation SBSR Adopting Release, 80 FR at 14701 nn. 1235 and 1236.

[174] *See infra* note 252.

[175] *See supra* section V.C (explaining that because the Commission believes that single-name CDS contracts make up a majority of security-based swaps, we have decided to use a conservative approach by estimating that the an equal number of respondents would be required to file at least one report related to CDS positions as would be required to file at least one report related to Security-Based Swap Positions consisting of other types of security-based swaps. The same rationale applies with respect to the estimated number of reports that the Commission would expect those respondents to file with respect to Security-Based Swap Positions consisting of security-based swaps based on equity securities and other debt securities (non-CDS).

[176] This estimate is based on the following: [(1,000 reports/week) × (52 weeks)] = 52,000 reports. In addition, the Commission previously estimated that 800 respondents will be subject to at least one reporting requirement pursuant to proposed Rule 10B–1. *See supra* section V.C. This estimate results in an average of 65 reports per respondent.

[177] *See* Proposed Collection; Comment Request; Extension: Regulation 13D and Regulation 13G, Schedule 13D and Schedule 13G; SEC File No. 270–137, 85 FR 25503 (May 1, 2020). The Commission recognizes that the 14.5 hour estimate for Schedule 13D is subsequently broken down based on the proportion of hours that would be carried internally by each respondent (25%), such that the other 75% would be carried by outside counsel (which was then monetized for purposes of the estimated burden). Because the Commission does not yet know what proportion of proposed Schedule 10B filings would be prepared externally, these estimates all assume that the entire 14.5 hour burden would be carried as *internal* costs by each respondent.

[178] *See* 15 U.S.C. 78c(f).

[179] *See* 15 U.S.C. 78w(a)(2).

burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

The analysis below addresses the likely economic effects of re-proposed Rule 9j–1, proposed Rule 10B–1, and proposed Rule 15Fh–4(c), including the anticipated benefits and costs of the rules and their likely effects on efficiency, competition, and capital formation. Many of the benefits and costs of re-proposed Rule 9j–1, proposed Rule 10B–1, and proposed Rule 15Fh–4(c) discussed below are difficult to quantify. For example, the Commission cannot quantify the impact of litigation and litigation risk to counterparties and underlying entities or the overall impact to the credibility and reputation of the security-based swap market. The extent of some of these impacts will depend, in part, on events difficult to predict that might affect security-based swaps such as changes in counterparty behavior. Reputational and credibility effects also are difficult to measure. Therefore, while the Commission has attempted to quantify economic effects where possible, much of the discussion of the anticipated economic effects below is qualitative and descriptive in nature.

B. Broad Economic Considerations

Credit Default Swaps

The single-name CDS market is a specialized venue for the transfer of credit, or default, risk of individual companies. This type of security-based swap allows market participants to obtain (or unload) exposure to the credit risk of an issuer without having to purchase (or sell) the issuer's bonds; the de-coupling allows for more precise targeting of credit risk exposure levels and lower transaction costs.[180] Active participants in the CDS market tend to be (a) highly-informed investors, such as hedge funds, pension funds, endowments, etc., that have a directional view on the economic prospects of an issuer; and (b) participants who have some natural exposure to the credit risk they want to hedge, such as ownership of the issuer's bonds or counterparty exposure to the issuer.[181] The latter category tends to include, for example, insurance companies, fixed-income investment funds, and broker-dealers. In general terms, the CDS market has the characteristics of a zero-sum game, where losses by one party to a transaction are offset by gains by the other party. The market provides incentives for participants to compete by leveraging marginal informational advantages, thereby forming information asymmetries among participants.

One example of material information that could lead to such an asymmetry is the trading characteristics of the issuer's related instruments, including the number of contracts that a market participant holds on a specific bond issue. This data is important because some market participants in the past have engaged in tactics that academics and media have described as ''opportunistic strategies.'' [182] Opportunistic strategies usually leverage large positions relative to the overall credit market for a specific issuer and can take a number of different forms. However, as a general matter, these strategies often involve CDS buyers or sellers taking steps, either with or without the participation of the underlying entity, to avoid, trigger, delay, accelerate, decrease, and/or increase payouts on CDS defaults. The larger the directional position, the greater the economic motivation to enter into these types of trades. When market participants employ one of these strategies, they intend to obtain gains from the positions they hold that go beyond those corresponding to the initial profit and loss expectation (the initial payoff function) at trade execution. This additional gain would be obtained to the direct detriment of a counterparty that is unaware of that additional loss potential.[183] Currently there is limited, if any, public information about the size of security-based swap positions held by a counterparty, so the average CDS market participant, despite being sophisticated and well-informed, is often unaware of the risk of being on the losing side of an opportunistic strategy. Because market participants could incur heavier-than-expected losses if their counterparty employed such a strategy, they may be disincentivized to participate in the market. This type of scenario—where a party's need to anticipate a bad outcome in a future transaction without full information could disincentivize certain behavior—is referred to as ''adverse selection.''

Adverse selection has been thoroughly documented in the economic literature, and its deleterious effects on market participation and efficiency are well known in sectors such as banking,[184] insurance,[185] and used cars.[186] Though the Commission lacks data that would show the direct link between the current CDS market condition (and the degree of adverse selection) and participants' appetite to trade, ''opportunistic strategies'' (which are symptomatic of a market with adverse selection) increase inefficiency in the market. To the extent that market participants anticipate ''opportunistic strategies,'' the CDS spread or price becomes a reflection of the likelihood of a ''manufactured'' strategy being announced (or, if already announced, of succeeding) and decouples from the credit fundamentals of the reference entity. This effect reduces the utility of the market as a venue to offload or take on the credit risk of a company because prices no longer reflect credit risk; *bona fide* hedgers or speculators in this market would be more likely to exit, as they cannot readily ''trade'' the credit of a company.[187]

Furthermore, the adverse selection problem in the CDS market runs in both directions. In contrast to the used car market, where the seller nearly always has more information and therefore the buyer must preempt the possibility of buying a ''lemon,'' in the CDS markets both buyers and sellers have the potential to leverage their market positions and engage in ''opportunistic

[180] CDS prices primarily relate to the credit risk component of a bond, while bond prices reflect both credit risk and the risk free rate. Hence, to replicate the bond, the CDS market participant needs exposure to both the CDS and the risk free bond, which has an additional cost.

[181] Martin Oehmke & Adam Zawadowski, The Anatomy of the CDS Market, 30 The Rev. of Fin. Stud., (Jan. 2017), at 80, 80–119 (*available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2023108*).

[182] Researchers, using a sample period from the fourth quarter of 2010 to the second quarter of 2018, have argued that these types of strategies have likely increased over time. *See* Danis & Gamba, supra note 22 at Figure 1.

[183] The market participant's gain from the transaction is inversely proportional to the gain of the counterparty, so the larger the market participant's position (and gain), the larger the counterparty's loss.

[184] Joseph E. Stiglitz & Andrew Weiss, Credit Rationing in Markets with Imperfect Information, 71 The Am. Econ. Rev., at 393 (June 1981) (presenting a model showing that, in a world with imperfect information, the use of interest rates or collateral in the screening process can introduce adverse selection and reduce overall expected loan profitability).

[185] *See* Amy Finkelstein & James M. Poterba, Adverse Selection in Insurance Markets: Policyholder Evidence from the U.K. Annuity Market, Nat'l Bureau of Econ. Rsch. NBER Working Paper, Paper No. 8045 (Dec. 2000), (*available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=489682*).

[186] George A. Akerlof, The Market for 'Lemons': Quality Uncertainty and the Market Mechanism, 84 Q. J. of Econ., at 488, 488–500 (Aug. 1970) (discussing a single-sided market for used cars where the seller is more informed then the buyer, leading to asymmetric information and potential market failure).

[187] *See* Fletcher, *supra* note 21 (explaining that ''engineered'' or ''manufactured'' transactions distort the information reflected in CDS spreads, to the point where the default risk expressed in CDS spreads is no longer connected to the financial condition of the underlying entity).

strategies,'' to the detriment of their counterparties.

In addition to the market imperfection mentioned above, the resemblance of a CDS contract to an insurance policy on an asset may give rise to information asymmetries amongst its counterparties. Since buying a CDS contract offers insurance to bondholders in the case of default, bondholders who buy CDS (pay a periodic premium) are less concerned about the health of the cash flows of the underlying asset, and in general less likely to renegotiate the terms in a bond contract.[188] This divergence in the expected outcomes of a transaction *after* a transaction occurs is called ''moral hazard'' or, specific to the CDS market, an ''empty creditor.'' [189] In this particular scenario, CDS sellers would likely prefer not to transact with such CDS buyers or could have trouble pricing this risk, to the extent they are unaware of which counterparty is such an empty creditor.[190] Additional information for market participants in the form of reporting, however, may also alleviate part of this information asymmetry [191] by making it easier for CDS sellers to identify such counterparties, thus mitigating the potential for moral hazard.

Total Return Swaps

The total return swap (TRS) [192] market differs from the CDS market in that the counterparties in a TRS take on the price and dividend risk of a reference stock and not the risk of default. Counterparties in the TRS market use the contracts to obtain exposure, usually leveraged, to the price movement and dividend payments of a stock or index and benefit from not having to own the stock itself. Market participants, such as mutual funds, hedge funds, and endowments, use TRS to obtain exposure in markets where they would face difficulties [193] purchasing or selling the underlying stock while taking advantage of the capital efficiencies of not holding shares in their inventories.

The risks attendant to the accumulation of large positions in TRS are different from CDS: With TRS, the main risk is that highly leveraged positions are very sensitive to price fluctuations of the underlying asset. The larger the position, the higher the risk that drastic price fluctuations may impair the solvency of the investor and, as a result, may create default risk for the security-based swap counterparty.

As in the CDS market,[194] the lack of public information about market positions means that market participants may not be aware of the risk of default of their counterparties, especially to those with concentrated, large positons who would be more prone to risks from price fluctuations. While counterparties could attempt to price in the risk of additional default risk, they currently lack the information necessary to accurately calculate the magnitude of that additional risk.

The existence of this information asymmetry that ensues from the party attaining the large position may create an economic externality. This externality is one where a market participant who decides to take on a large leveraged position in the underlying entity through a TRS will not internalize the total societal cost of a negative outcome where it declares bankruptcy. When the market participant amassing the large position fails, the costs of the participant's behavior on the issuer of the security, its counterparty, and the reputation of the market could be larger than those internalized by the failing party. Reporting could alleviate the externality by making information public that could be incorporated into TRS prices, thus requiring the party with the equity exposure to fully pay for the additional risks that it is incurring. Counterparties that have amassed large economic exposures in a specific security or TRS on that security (or both) and are therefore at greater risk of default could then be more easily identified.

C. Baseline

1. Existing Regulatory Frameworks

As discussed in section I.A, because security-based swaps are included in the Exchange Act's definition of ''security,'' participants in the SBS market are currently subject to the general antifraud and anti-manipulation provisions of the Federal securities laws, including Sections 9(a), 10(b) and Rule 10b–5 under the Exchange Act, and Section 17(a) of the Securities Act. In addition, the Dodd-Frank Act expanded the anti-manipulation provisions of Section 9 of the Exchange Act to encompass security-based swap transactions and requires the Commission to adopt rules to prevent fraud, manipulation, and deception in connection with security-based swaps.[195]

In addition, the Commission has now finalized a majority of its Title VII rules related to SBS Entities, including rules that allow such persons to manage the market, counterparty, operational and legal risks associated with their security-based swap business. These include the Risk Mitigation Rules; rules relating to capital, margin, and segregation requirements for SBSDs, MSBSPs, and broker-dealers (the ''Capital, Margin, and Segregation Rules''); [196] and rules relating to recordkeeping and reporting requirements for SBSDs, MSBSPs, and broker-dealers (the ''Recordkeeping Rules'').[197] The Risk Mitigation Rules, which consist of 17 CFR 240.15Fi–3 (''Rule 15Fi–3''), 17 CFR 240.15Fi–4 (''Rule 15Fi–4''), and Rule 15Fi–5, relate to, other things, reconciling outstanding security-based swaps with applicable counterparties on a periodic basis, engaging in certain forms of portfolio compression exercises, as appropriate, and executing written security-based swap trading relationship documentation with each of its counterparties prior to, or contemporaneously with, executing a security-based swap transaction. When the Commission adopted those rules in December 2019, we explained that they were intended to play an important role in addressing risks to an SBS Entity as a whole, including risks related to the

[188] Bolton & Oehmke, *supra* note 112 at 2617, 2617–2655; *see also* András Danis, Do Empty Creditors Matter? Evidence from Distressed Exchange Offers, 63 Mgmt Sci., at 1271, 1271–1656 (Oct. 2015) (*available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2001467*).

[189] Bengt Holmström, Moral Hazard and Observability, 10 The Bell J. of Econ., at 74, 74–91 (Spring, 1979).

[190] There is evidence that even sophisticated market participants were unable to ex-ante price events characterized as ''empty creditor'' scenarios. *See Solus Alternative Asset Management LP* v. *GSO Capital Partners L.P.,* No. 18 CV 232–LTS–BCM (SDNY Jan. 29, 2018).

[191] The additional reporting could inform the market of the filer's interest in the underlying entity's solvency by allowing the observance of a conventional, hedging CDS position. For example, a CDS participant with a large long CDS position may be less interested in the underlying entity's solvency as compared to the issuing entity itself or to a bond investor without CDS insurance. Further, to the extent that a counterparty has not reported pursuant to the proposed rule, a market participant could infer information about a potentially lower level of risk associated with transacting with that counterparty.

[192] TRS include non-CDS debt-based security swaps, equity-based security swaps, and mixed swaps.

[193] A market participant may find it difficult to buy stock of a foreign company, or may have trouble locating a stock to sell short.

[194] Navneet Arora, Priyank Gandhi & Francis A. Longstaff, Counterparty Credit Risk and the Credit Default Swap Market, 103 J. of Fin. Econ., at 280, 280–293 (March 1, 2011) (*available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1830321*) (arguing that, ''[they] find that counterparty credit risk is priced in the CDS market.'').

[195] *See supra* note 5 and accompanying text.

[196] *See* Capital, Margin, and Segregation Adopting Release, 84 FR 43872.

[197] *See* Recordkeeping and Reporting Adopting Release, 84 FR 68550.

entity's safety and soundness.[198] For example, portfolio reconciliation is designed to allow SBS Entities to manage their internal risks by better ensuring agreement with their counterparties with respect to the material terms and valuation of each transaction (and thereby avoiding complications at various points throughout the life of the transaction).[199] Further, requiring an SBS Entity to document the terms of the trading relationship with each of its counterparties before executing a new security-based swap transaction should promote sound collateral and risk management practices by enhancing transparency and legal certainty regarding each party's rights and obligations under the transaction.[200] Similarly, portfolio compression, by allowing an SBS Entity to potentially eliminate offsetting and redundant uncleared derivatives transactions—as measured both by the number of contracts and the total notional value—reduces its gross exposure to its direct counterparties, including by eliminating all exposure (and credit risk) to certain counterparties.[201]

The Capital, Margin, and Segregation Rules, among other things: (1) Established minimum capital requirements for non-bank SBSDs and MSBSPs (*i.e.,* SBSDs and MSBSPs for which there is not a prudential regulator); (2) increased the minimum tentative net capital and net capital requirements for broker-dealers that use internal models to compute net capital; (3) established capital requirements tailored to security-based swaps and swaps for broker-dealers that are not registered as an SBSD or MSBSP to the extent they trade these instruments; and (4) established margin requirements for non-bank SBSDs and MSBSPs with respect to non-cleared security-based swaps.[202] That rulemaking also established segregation requirements for SBSDs and notification requirements with respect to segregation for SBSDs and MSBSPs.[203]

When the Commission adopted the Capital, Margin, and Segregation Rules, we explained that the capital requirements were designed to ensure that non-bank SBSDs and stand-alone broker-dealers, respectively, have sufficient liquidity to meet all unsubordinated obligations to customers and counterparties and, consequently, if the non-bank SBSD or stand-alone broker-dealer fails, sufficient resources to wind-down in an orderly manner without the need for a formal proceeding.[204] Similarly, in the course of discussing the margin requirements, the Commission explained that ''[i]n the market for non-cleared security-based swaps and in the market for OTC derivatives generally, collateral is the means for mitigating counterparty credit risk.'' [205] Finally, the Commission explained that segregation requirements were designed ''to protect the rights of security-based swap customers and their ability to promptly obtain their property from an SBSD or stand-alone broker-dealer.'' [206]

The Commission's Recordkeeping Rules also play an important role in reducing certain types of risk. Among other things, those rules, which also were adopted in 2019, establish recordkeeping, reporting, and notification requirements for SBSDs and MSBSPs and securities count requirements for stand-alone SBSDs, and also establish additional recordkeeping requirements applicable to stand-alone broker-dealers to the extent they engage in security-based swap or swap activities.[207] Many of those rules have been designed expressly to ''promote compliance with the financial responsibility requirements for broker-dealers, SBSDs, and MSBSPs, facilitate regulators' oversight and examinations of such firms, and promote transparency of their financial condition and operation.'' [208]

Market participants are already subject to the requirements of Regulation SBSR, which governs regulatory reporting of security-based swap transactions to SBSDRs. Regulation SBSR provides for real-time public reporting of individual security-based swap transactions to a SBSDR within 24 hours of the trade execution and the immediate public dissemination by the SBSDR of security-based swap transaction information, including pricing and volume information. Regulation SBSR requires certain items to be reported about each security-based swap transaction, such as the ''product ID'' [209]; date and time of the transaction; price and amount of up-front payments; notional amount; indication of whether the transaction will be submitted to clearing; and identification of the parties to the transaction. On November 8, 2021, mandatory reporting of new security-based swap transactions to SBSDRs began, with public dissemination of those transactions set to begin on February 14, 2022.[210] As of November 9, 2021, there are currently two registered SDRs: DTCC Data Repository (''DDR'') and ICE Trade Vault (''ITV''). As discussed above, any position reporting pursuant to Regulation SBSR is completely anonymous, and would therefore not inform participants that a specific counterparty was building up large, concentrated security-based swap positions.[211]

In addition, section 30(b) and 17 CFR 270.30b1–9 (''Rule 30b1–9'') of the Investment Company Act of 1940 require that registered investment companies and certain exchange-traded funds report information quarterly about their portfolios and each of their portfolio holdings, including security-based swaps, as of the last business day, or last calendar day, of each month. With the exception of certain non-public information, the information reported on Form N–PORT for the third month of each fund's fiscal quarter is made publicly available.

Finally, Rule 15Fk–1 requires an SBS Entity to designate a CCO and imposes certain duties and responsibilities on that CCO.[212] Further, existing rules require that a majority of the board approve the compensation and removal of the CCO.[213] Rule 15Fh–4(a) makes it unlawful for an SBS Entity to: (i) Employ any device, scheme, or artifice to defraud any special entity or prospective customer who is a special entity; (ii) engage in any transaction, practice, or course of business that operates as a fraud or deceit on any special entity or prospective customer

[198] *See* Risk Mitigation Adopting Release, 85 FR at 6378–79.

[199] *See* Risk Mitigation Adopting Release, 85 FR at 6361.

[200] *See id.* Both of the portfolio reconciliation and documentation requirements should also help to reduce counterparty credit risk and promote certainty regarding the agreed upon valuation and other material terms of a security-based swap. *See id.*

[201] *See id.*

[202] *See* Capital, Margin, and Segregation Adopting Release, 84 FR at 43874.

[203] *See id.*

[204] *See* Capital, Margin, and Segregation Adopting Release, 84 FR at 43959.

[205] *See* Capital, Margin, and Segregation Adopting Release, 84 FR at 44012.

[206] *See* Capital, Margin, and Segregation Adopting Release, 84 FR at 43959.

[207] *See* Recordkeeping and Reporting Adopting Release, 84 FR at 68607.

[208] *See id.*

[209] The term ''product ID'' is defined in Regulation SBSR to mean the ''unique identification code'' assigned to a product. *See* 17 CFR 242.900(bb) (defining ''product ID'') and 900(qq) (defining ''unique identification code''). Pursuant to Rule 901(c)(1) of Regulation SBSR, if there is no product ID, the reporting party is required to report certain information about the security-based swap, including, among other things, the asset class of the security-based swap, the specific underlying security, effective date, termination date, and certain payment terms.

[210] *See* 17 CFR 242.901(c).

[211] *See supra* note 5 and accompanying text.

[212] *See* 17 CFR 240.15Fk–1.

[213] *See supra* section II.D.

who is a special entity; or (iii) to engage in any act, practice, or course of business that is fraudulent, deceptive, or manipulative. Further, existing Rule 15Fh–3(h) requires an SBS Entity to establish and maintain a system to supervise its business and the activities of its associated persons; the system must be reasonably designed to prevent violations of the provisions of applicable Federal securities laws and the rules and regulations thereunder.[214] In addition, the Commission's Risk Mitigation Rules are designed to foster effective risk management by requiring the existence of sound documentation, periodic reconciliation of portfolios, rigorously tested valuation methodologies, and sound collateralization practices.[215] Attempts by officers, directors or employees to hide transactions, submit false valuations or manipulate or fraudulently influence CCOs in the performance of their duties related to the Risk Mitigation Rules would undermine the SBS Entity's risk management.[216]

2. Security-Based Swap Data, Market Participants, Dealing Structures, Levels of Security-Based Swap Trading Activity, and Position Concentration

As of November 9, 2021, there are 41 entities registered with the Commission as SBSDs, and no entities have registered as MSBSPs. According to data published by the Bank for International Settlements (''BIS''), as of December 2020, there was approximately: (i) $3.5 trillion [217] in global notional amount outstanding of single-name CDS; (ii) $4.5 trillion in multi-name index CDS outstanding; and (iii) $347 billion in multi-name, non-index CDS outstanding.[218] The total gross market value outstanding in single-name CDS was approximately $77 billion, and in multi-name CDS instruments, there was approximately $125 billion outstanding. The global notional amount outstanding in equity forwards and swaps was $3.6 trillion, with total gross market value of $321 billion.[219]

The above-described data is provided on an aggregate and global basis. The Commission's primary source for disaggregated transactions and positions in the market for security-based swaps is the DTCC Derivatives Repository Limited Trade Information Warehouse (''DTCC–TIW''). DTCC–TIW provides data regarding the activity of market participants in the single-name CDS market during the period from 2006 to the end of 2020.[220] The Commission acknowledges that limitations in the data constrain the extent to which it is possible to quantitatively characterize the security-based swap market.[221] Based on an analysis of DTCC–TIW data, staff concluded that there are 2,321 transacting agents that engaged directly in trading between November 2006 and December 2020 with 15,187 accounts.[222]

Data from the DTCC–TIW show that activity in the single-name CDS market is concentrated among a relatively small number of entities, predominantly ISDA-recognized dealers and large banks, who act as dealers in this market.[223] The top five dealers (when accounts are sorted by number of counterparties) when combined transact with over a thousand counterparty accounts, consisting of both other dealers and non-dealers. The next 23% of dealers transacted with 500 to 1,000 counterparty accounts; 38% transacted with 100 to 500 unique accounts; and 31% of dealer accounts intermediated security-based swaps with fewer than 100 unique counterparties accounts in 2020. The median number of counterparty accounts across dealers is 276 (the mean is approximately 570). Dealer-intermediated transactions reached a gross notional amount of approximately $1.99 trillion, approximately 55% of which was intermediated by the top five dealer accounts. The median non-dealer counterparty transacted with only two dealer accounts (with an average of approximately 2.5 dealer accounts) in 2020.

Non-dealer single-name CDS market participants include, but are not limited

[214] *See* 17 CFR 240.15Fh–3(h).

[215] *See* Risk Mitigation Adopting Release, 85 FR 6359.

[216] *See supra* section II.D.

[217] The global notional amount outstanding represents the total face amount used to calculate payments under outstanding contracts. The gross market value is the cost of replacing all open contracts at current market prices.

[218] *See* BIS, Semi-annual OTC derivatives statistics at December 2020, Table D5.2, (*available at: https://stats.bis.org/statx/srs/table/d5.2* (accessed Aug. 18, 2021).

[219] These totals include swaps and security-based swaps, as well as products that are excluded from the definition of ''swap,'' such as certain equity forwards. *See* OTC, equity-linked derivatives statistics, Table D5.1, *available at https://stats.bis.org/statx/srs/table/d5.1* (accessed Aug. 18, 2021). For the purposes of this analysis, the Commission assumes that multi-name index CDS are not narrow-based index CDS and therefore, do not fall within the 'security-based swap' definition. *See* 15 U.S.C. 78c(a)(68)(A); *see also* Products Release, 77 FR 48208. The Commission also assumes that all instruments reported as equity forwards and swaps are security-based swaps, potentially resulting in underestimation of the proportion of the security-based swap market represented by single-name CDS. Therefore, when measured on the basis of gross notional outstanding single-name CDS contracts appear to constitute roughly 49% of the security-based swap market. Although the BIS data reflect the global OTC derivatives market, and not just the U.S. market, the Commission has no reason to believe that these percentages differ significantly in the U.S. market. Note that these data do not include TRS on debt which are covered by the proposal.

[220] DTCC Derivatives Repository Limited Trade Information Warehouse provides weekly positions and monthly transaction files on a voluntary basis for single-name and index-based CDS. These data cover all positions and transactions where one of the counterparties is a U.S. entity or the reference entity is U.S. entity, with status as a U.S. entity determined by DTCC–TIW. In DTCC–TIW, the Commission observes end of week CDS positions for all U.S. entities, foreign counterparties to a U.S. entity, or foreign counterparties trading a CDS referencing a U.S. underlying entity. The DTCC–TIW data have limitations. Data do not address two foreign counterparties with CDS referencing foreign underlying entities. In addition, the DTCC–TIW data does not provide any intra-weekly CDS position information, nor any information on the underlying security holdings of reference entities. Further, DTCC–TIW is a voluntary database where market participants on a voluntary basis submit transactions, and end of week holdings.

[221] While the Commission has limited data regarding the activity of market participants in equity swaps, the Commission believes that the market for security-based swaps is sufficiently representative of the market. DTCC Derivatives Repository Limited Trade Information Warehouse provides weekly positions and monthly transaction files on a voluntary basis for single-name and index-based CDS. These data cover all positions and transactions where one of the counterparties is a U.S. entity or the reference entity is U.S. entity, with status as a U.S. entity determined by DTCC–TIW. The Commission also relies on qualitative information regarding market structure and evolving market practices provided by commenters and the knowledge and expertise of Commission staff.

[222] These 2,321 entities, which are presented in more detail in Table 1, below, include all DTCC–TIW-defined ''firms'' shown in DTCC–TIW as transaction counterparties that report at least one transaction to DTCC–TIW as of December 2017. The staff in the Division of Economic and Risk Analysis classified these firms, by machine-matching names to known third-party databases and by manual classification. *See, e.g.,* Dealing Activity Adopting Release, 81 FR 8602, n.43. Manual classification was based in part on searches of the EDGAR and Bloomberg databases, the SEC's Investment Adviser Public Disclosure database, and a firm's public website or the public website of the account represented by a firm. As mentioned above, data on CDS market participants come from DTCC–TIW. Principal holders of CDS risk exposure are represented by ''accounts'' in the DTCC–TIW. ''Accounts'' as defined in the DTCC–TIW context are not equivalent to ''accounts'' in the definition of ''U.S. person'' provided by Exchange Act rule 3a71–3(a)(4)(i)(C). One entity or legal person (known as ''transacting agent'' in the terminology of TIW) may have multiple accounts. For example, a bank that is a transacting agent may have one DTCC–TIW account for its U.S. headquarters and one DTCC–TIW account for one of its foreign branches.

[223] Dealers are generally persons engaged in the business of buying and selling securities for their own account, through a broker or otherwise. 15 U.S.C.78c(a)(5). Security-based swap dealers are generally defined as persons who hold themselves out as dealers in security-based swaps; make markets in security-based swaps; regularly enter into security-based swaps as an ordinary course of business for their own account; or engages in any activity causing them to be commonly known in the trade as a dealer or market maker in security-based swaps. 17 CFR 240.3a71–1.

to, investment companies, pension funds, private funds, sovereign entities, and industrial companies. We observe that most non-dealer market participants of single-name CDS do not engage directly in the trading of security-based swaps, but trade through banks, investment advisers or funds, or other types of firms, which we refer to as transacting parties, consistent with DTCC–TIW terminology.[224] As shown in Table 1, close to 78 percent of transacting parties are identified as investment advisers or funds, of which approximately 40 percent (about 32 percent of all transacting parties) are registered as investment advisers under the Advisers Act.[225] Although investment advisers and funds are the vast majority of transacting parties, the transactions they executed account for only 9.5 percent of all single-name CDS trading activity reported to the DTCC–TIW, measured by the number of transaction sides.[226] The vast majority of transactions, 82.1 percent, measured by number of transaction-sides were executed by ISDA-recognized dealers.

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Table 1. The number of transacting parties by counterparty type and the fraction of total trading activity, from November 2006 through December 2020, represented by each counterparty type.

	Total Number of transacting parties	Percent	Total Transaction Share	Number of US Firms	Percent	US Transaction Share
Investment Advisers/Funds [a]	1,823	78.5%	14.2%	1,052	91.8%	18.5%
- *SEC registered (IA)*	*734*	*31.6%*	*9.5%*	*619*	*54.0%*	*13.3%*
- *Mutual funds and ETFs*	*411*	*17%*	*6%*	*334*	*29%*	*5%*
Banks (excluding G16)[b]	274	11.8%	3.3%	13	1.1%	0.0%
Pension Funds	30	1.3%	0.1%	2	0.2%	0.0%
Insurance Companies	48	2.1%	0.2%	30	2.6%	0.3%
ISDA - Recognized Dealer[c]	17	0.7%	82.1%	7	0.6%	81.2%
others	129	5.6%	0.2%	42	3.7%	0.1%
Total	2,321	100.0%	100%	1,146	100.0%	100%

[a] Investment Adviser/Funds – For purposes of this table, these entities have the following characteristics: clients are predominantly individuals, institutions, investment companies, pensions and profit sharing, registered investment companies, pensions and that take public and institutional money. Some also manage pooled investment vehicles (e.g., hedge funds), private equity and venture capital.

[b] Banks (excluding G16) - The primary characteristic is the entity is trading on its own account and not just on behalf of its clients. This includes depository institutions, swaps dealers (market makers), and classically-defined investment banks.

[c] ISDA recognized dealer – market maker (dealers) identified by ISDA as belonging to the G14 or G16 dealer group during the period. See, e.g., https://www.isda.org/a/5eiDE/isda-operations-survey-2010.pdf.

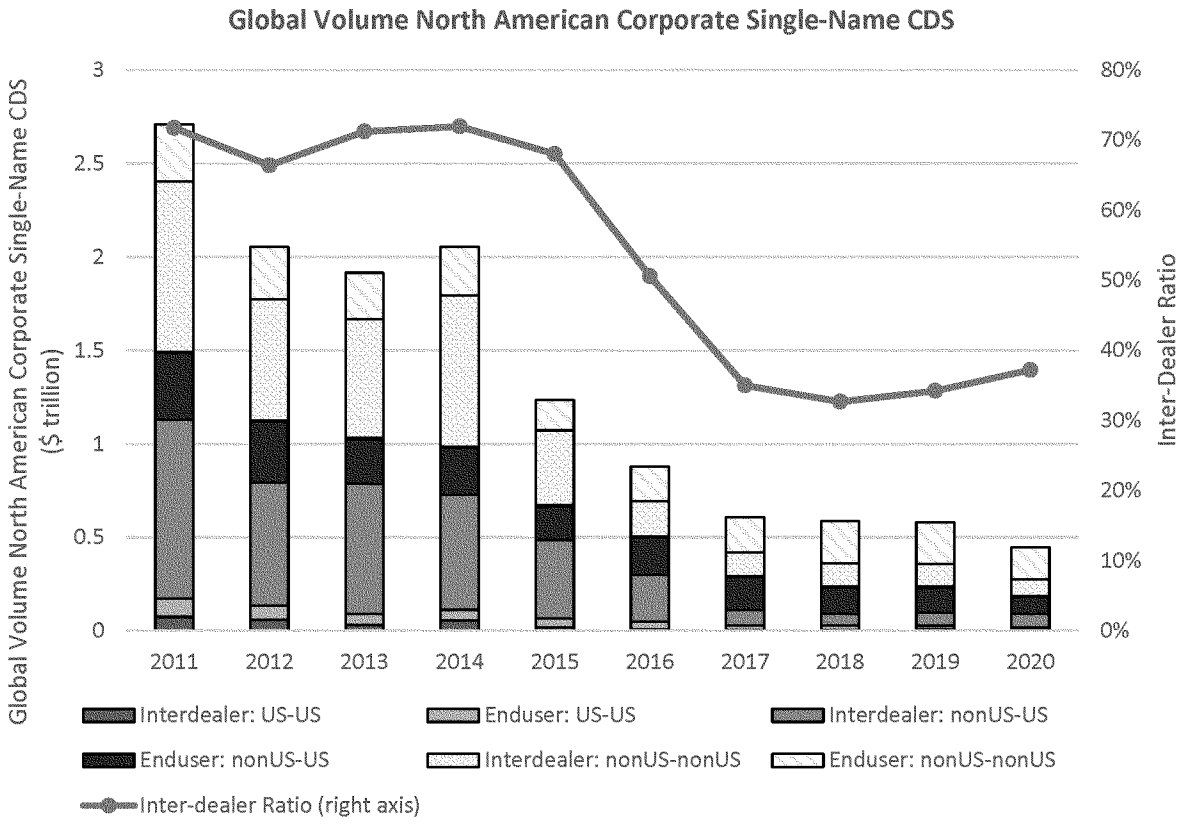
Figure 1 describes the percentage of global, notional transaction volume in North American corporate single-name CDS reported to the DTCC–TIW from January 2011 through December 2020, separated by whether transactions are between two ISDA-recognized dealers (interdealer transactions) or whether a transaction has at least one non-dealer counterparty. As proposed Rule 10B–1 would affect U.S. market participants as well as foreign entities who trade in both the security-based swap and underlying asset, Figure 1 compares the notional trading volume of all North American corporate single-name CDS to notional trading of U.S. counterparties. The observed declining trend seems to impact proportionally all types of exposures. As Figure 1 shows, all types of exposures have declined approximately proportionally since 2011.

[224] *See* 15 U.S.C. 80b1 through 80b21. Transacting parties participate directly in the security-based swap market, without relying on an intermediary, on behalf of their principals, investment companies, pension funds, private funds, sovereign entities, and industrial companies. For example, a university endowment may hold a position in a security-based swap that is established by an investment adviser that transacts on the endowment's behalf. In this case, the university endowment is a principal that uses the investment adviser as its transacting party.

[225] DTCC-defined ''firms'' shown in DTCC–TIW, which we refer to here as ''transacting parties.''

[226] Each transaction has two transaction sides, *i.e.,* two transaction counterparties.

Figure 1: Global, notional trading volume in North American corporate single-name CDS by calendar year and the fraction of volume that is inter-dealer.[a]



[a] Same-day cleared trades are assumed to be either inter-dealer or between a dealer and an end-user (as security-based swap transactions between two end-users are rare in both the cleared and un-cleared markets).

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As mentioned above, DTCC–TIW data covers only CDS positions. However, the Commission staff has access to some information on affected parties using filings from Form N–PORT. As discussed above, certain registered investment companies must report information quarterly about their portfolios to the Commission in Form N–PORT. DTCC–TIW data is summarized in Table 1, indicate that in the CDS market, mutual funds and Exchange Traded Funds (ETFs) that report on Form N–PORT represent approximately 17% of firms in DTCC–TIW, and make up approximately 6% of all transactions available in DTCC–TIW.[227] As a percentage of US-only firms, mutual funds and ETFs that report on Form N–PORT represent approximately 29% of firms in the U.S. and approximately 5% of total U.S. transactions reported in DTCC–TIW. These transactions provide a sample of the entities participating in the CDS market that are mutual funds and ETFs, which are required to file Form N–PORT.[228]

D. Consideration of Costs and Benefits; Consideration of Burden on Competition and Promotion of Efficiency, Competition and Capital Formation

1. *Re-proposed Rule 9j–1 and Proposed Rule 15Fh–4(c)*

i. *Benefits*

The Commission believes that re-proposed Rule 9j–1 would decrease fraudulent activity, affect compliance costs, and lower litigation costs. In addition, re-proposed Rule 9j–1 may indirectly increase price efficiency and decrease capital costs of underlying entities. The Commission discusses each of these individual benefits in more detail below.

The Commission believes that re-proposed Rule 9j–1 would reduce the risk of fraud in the security-based swap market, including risk of fraudulent behavior undertaken in connection with opportunistic trading strategies. The additional specificity offered by re-proposed Rule 9j–1 may enhance Commission oversight of the security-based swap market, which may ultimately benefit market participants through reducing the risk of fraud. Further, by reducing these risks, re-proposed Rule 9j–1 could encourage participation in the market, which may result in increased competition.[229] More security-based swap entities would be willing to supply (issue) and/or demand (buy) security-based swaps, with increased confidence that their

[227] The analysis in Table 1 using DTCC–TIW data is performed on transacting party level, while analysis of Form N–PORT data is performed at fund level. Due to data limitations and no direct linkages between DTCC–TIW and N–PORT data, the Commission cannot directly compare entities reporting to DTCC–TIW to entities that file Form N–PORT.

[228] Form N–PORT is to be used by a registered management investment company, or an exchange-traded fund organized as a unit investment trust, or series thereof (''Fund''), other than a Fund that is regulated as a money market fund (''money market fund'') under 17 CFR 270.2a–7 (''Rule 2a–7'') under the Investment Company Act of 1940, 15 U.S.C. 80a (''Act'') or a small business investment company (''SBIC'') registered on Form N–5 (17 CFR 239.24 and 274.5), to file reports of monthly portfolio holdings pursuant to Rule 30b1–9 under the Act (17 CFR 270.30b1–9).

[229] *See* Joint Statement, *supra* note 29.

counterparties would have limited abilities to impact the market using, among other things, opportunistic strategies.

The Commission also believes that, by providing additional precision and specificity regarding the application of existing antifraud and anti-manipulation laws to misconduct in the security-based swap market, re-proposed Rule 9j–1 could prompt some market participants to devote greater resources to ensure that they are compliant with their obligations under antifraud and anti-manipulation law, which could also decrease the risk of fraud in the security-based swap market. Because of this decreased risk of fraud, market participants may have fewer disputes with their counterparties regarding security-based swap contracts, which in turn, could lower litigation costs for security-based swap participants and underlying entities. Lower litigation costs could contribute to reducing the cost of CDS and, to the extent that the cost of CDS is reduced, lower costs of borrowing. Conversely, by providing additional precision and specificity regarding the application of existing antifraud and anti-manipulation provisions of the Federal securities laws to misconduct in the security-based swap market, the re-proposed Rule 9j–1 could decrease compliance costs for some market participants who may, as a result of the additional specificity of the rule, need to spend fewer resources determining appropriate compliance under Section 9(j).

Decreased risk of fraud, including risk of fraudulent behavior undertaken in connection with opportunistic trading strategies, in the security-based swap market may also lead to increased price efficiency, as new trading could lead to a greater exchange of market expectations from buyers and sellers transacting in the market. This would consequently lead to greater security-based swap market efficiency, as security-based swap prices would provide greater confidence that their prices more likely reflect fundamental values and risk in more liquid markets. For example, prices of single-name CDS contracts would more likely reflect the fundamental credit risk of the underlying entity, as opposed to counterparty credit risk or the probability that an ''opportunistic'' or ''manufactured credit'' strategy were successful.[230] Further, by providing specificity, re-proposed Rule 9j–1 would help prevent prohibited conduct from distorting the market and artificially increasing or decreasing prices for security-based swaps. Thus, we believe the proposed rules would help to ensure more efficient pricing.

In addition, the Commission expects the price efficiency in the underlying securities markets to have a positive impact on capital formation and the cost of capital for the underlying entities. The market participation increases in security-based swaps may enhance liquidity in the underlying market and related swap indices, and in general, lower debt and equity capital costs for security-based swaps referenced entities. For example, if prices of single-name CDS are more reflective of the fundamental credit risk of the underlying entity, as a second order effect, participants in the market for the underlying security would be better informed about the underlying security's attributes through the price signal, likely increasing their willingness to re-enter or engage in the underlying security's market. Specifically, the underlying security market uses the derivative market to assess its quality, as the derivative market in some circumstances is forward looking, liquid, and more informative than the underlying market.[231] Greater activity in the underlying security market due to price efficiency and greater availability to hedge these securities in the security-based swap market could lead to lower capital costs and increase capital formation for the underlying entities.

Proposed Rule 15Fh–4(c) would make it unlawful for any officer, director, supervised person, or employee of an SBS Entity, or any person acting under such person's direction, to directly or indirectly take any action to coerce, mislead, or otherwise interfere with the SBS Entity's CCO. This prohibition would support the ability of the CCO to meet the CCO's important obligations to foster compliance in its role of overseeing compliance within the SBS Entity. We expect that this rule change would make it more likely that a CCO would be able to more efficiently and effectively execute the CCO's responsibilities to foster compliance, including for example, by ensuring that the SBS Entity maintains and reviews written policies and procedures reasonably designed to achieve compliance with the rules and regulations relating to the business of the security-based swap entity. Ultimately, we expect that these effects would likely also reduce the risk of fraud, market manipulation, or other fraudulent activities in the security-based swap market, providing additional protection for both counterparties in the security-based swap transaction and the underlying entity.

Proposed Rule 15Fh–4(c) would likely have minor indirect positive impacts on price efficiency, competition, and capital formation. Because Rule 15Fh–4(c) would support the ability of the CCO to oversee compliance with the federal securities laws within the SBS Entity and likely reduce the risk of fraud, security-based swaps would be more likely to be reflective of the fundamental credit risk of the underlying entity, positively influencing price efficiency and competition among market participants. Capital formation could, as a result, further indirectly increase, as greater price efficiency and competition among market participants could lead to a decrease in security-based swaps prices, in turn, lower costs of borrowing (as a result of cheaper CDS).

ii. Costs

Some security-based swap market participants may incur costs associated taking actions to update existing compliance systems for compliance with re-proposed Rule 9(j)–1. We expect, however, that these additional costs would be relatively small because many of these practices and systems are already in place to ensure compliance with Section 9(j) of the Exchange Act and the other general antifraud and anti-manipulation statutory and regulatory provisions.[232]

In addition, the proposed rule could discourage some legitimate market activities, including some hedging activity, because of concerns that such activities might be viewed as rule violations. As a result, compliance costs related to evaluating whether or not

[230] *See* Fletcher, *supra* note 21.

[231] *See* Haibin Zhu, An Empirical Comparison of Credit Spreads between the Bond Market and the Credit Default Swap Market, EFMA 2004 Basel Meetings Paper, BIS Working Paper No. 160, (Aug. 2004) (*available at: https://ssrn.com/abstract=477501*); *see also* Jongsub Lee, Andy Naranjo, and Guner Velioglu, When do CDS Spreads Lead? Rating Events, Private Entities, and Firm-specific Information Flows, 13 J. of Fin. Econ., 556, at 556–578 (2017) (*available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2933052*) (addressing the size of US single-name reference entities).

[232] As noted above, some commenters to the 2010 proposed rule argued that not requiring scienter with respect to paragraphs (3) and (4) of re-proposed Rule 9j–1(a) (which were paragraphs (c) and (d) in the 2010 proposed rule) ''could potentially deter many parties from entering into SBS, increase their cost and have other distorting effects on the markets.'' Because Rule 9j–1(a), as discussed above, does not apply a new scienter standard to market conduct, we do not expect such increases in costs or distorting effects on the market. *See supra* section II.B.1.

certain activities are permissible may increase for some market participants. However, because re-proposed Rule 9j–1 would provide additional precision and specificity regarding the application of existing antifraud and anti-manipulation laws to misconduct in the security-based swap market, the Commission believes that these costs would not be significant. Further, these costs would be mitigated to the extent that the limited safe harbor from certain provisions of re-proposed Rule 9(j)–1 addresses situations in which a counterparty is required to take certain pre-agreed actions with respect to the security-based swap, or to effect certain transactions related to portfolio compression exercises, in each case while in possession of material non-public information.

Proposed Rule 15Fh–4(c)'s prohibition on taking actions to coerce, mislead, or otherwise interfere with the SBS Entity's CCO, may create additional costs for SBS Entities. For example, to the extent that any current practices of an SBS Entity may include activities that would be explicitly prohibited under Rule 15Fh–4(c), applicable policies and procedures would need to be updated. In addition, it is possible that the proposed rule could cause SBS Entity employees to be overly cautious when consulting with a CCO. We do not, however, believe that any such effects will be significant, given the specificity of the rule's prohibition on certain interference with the SBS Entity's CCO.

2. Proposed Rule 10B–1

i. Benefits

Proposed Rule 10B–1 could increase market integrity, increase liquidity, decrease counterparty risk, lower litigation costs, decrease cost of capital for underlying entities, decrease contagion risk in the market, and assist the Commission in identifying concentrated position and holdings in related securities. We discuss each of these benefits below.

The Commission expects proposed Rule 10B–1 reporting requirements to enhance the integrity of the security-based swap market. The proposed reporting requirements would inform market participants of large concentrated positions that might give the holder incentives to affect the timing or the payoff size of the CDS contract for the CDS buyer's benefit. As a result, market participants would be better able to assess counterparty risk. In this respect, the Commission recognizes that the Risk Mitigation Rules; Capital, Margin, and Segregation Rules; and Recordkeeping Rules may address similar risks, to the extent that these rules are intended to, among other things, promote safety and soundness of SBS Entities, enhance the transparency of obligations under transactions with SBS Entities, protect the ability of security-based swap customers to promptly obtain their property, and promote compliance with financial responsibility requirements for broker-dealers, SBSDs, and MSBSPs. However, because of proposed Rule 10B–1's application to non-SBS Entities, in addition to SBS Entities, and the proposed rule's reporting-based method to the reduction of counterparty risk, the proposed rule would afford additional protections to market participants, including with respect to large position concentration risk. In contrast to the Risk Mitigation Rules; Capital, Margin, and Segregation Rules; and Recordkeeping Rules, proposed Rule 10B–1 would provide information to market participants for them to take specific mitigating actions to limit counterparty risk exposure.

Further, to the extent that market participants are better able to assess counterparty risk as a result of the reporting that would be required under proposed Rule 10B–1, it would likely become more expensive to build such positions, because market participants may refrain from trading with a reporting counterparty, trade only at prices that account for additional risk, or ask for larger margin postings of collateral. These actions would likely make it unprofitable to create market conditions that would impact the timing or the size payoff of the CDS contract. Further, because the reporting required under proposed Rule 10B–1 would inform the Commission of material, directional positions, it may enhance Commission oversight of the security-based swap market, which may ultimately benefit market participants. In particular, it would provide the Commission tools to monitor for large concentrated positions, counterparty risk, and potentially detect fraudulent behavior, as the Commission would have access and complete visibility to both the security-based swap and the related underlying asset for participants that would be required to report.

Because proposed Rule 10B–1 would make it more challenging to create market conditions that would affect the timing or the size payoff of the CDS contract, proposed Rule 10B–1 would likely result in greater overall market integrity. Through better information for market participants, the Commission expects proposed Rule 10B–1 to encourage participants to increase capital buffers (*i.e.,* both initial and variation margins) where needed and help to prevent the impact of defaults from spreading through exposed counterparties, thereby limiting ''contagion risk'' (*i.e.,* risk that might result from indirect counterparty risk) in the market.

Further, by requiring large CDS buyers to report their positions, proposed Rule 10B–1 may help reduce the presence of moral hazard in single-name CDS markets. As described in the Broad Economic Considerations, in the presence of asymmetric information, bondholders who are also CDS buyers may become disinterested in the solvency of the underlying asset, and may become less inclined to renegotiate contracts in order to avoid a default in bond payments. Proposed Rule 10B–1 would benefit market participants by requiring reporting of large CDS positions and allowing market participants to identify counterparty risk, adjust prices for counterparty risk, and limit the scope of moral hazard.

Such increases in market integrity may allow market participants to trade with more and with greater confidence in the market. As a result, proposed Rule 10B–1 could lead to increased supply and demand for security-based swaps, leading to greater competition as more security-based swap market participants enter the market. Further, this would consequently lead to greater security-based swap market efficiency, as security-based swap prices would more likely reflect fundamental values and risk in more liquid markets. For example, prices of single-name CDS contracts would more likely reflect the fundamental credit risk of the underlying entity. Thus, we expect the proposed rules would help to ensure more efficient pricing in the security-based swap market. Price efficiency would increase, as participants would be better informed of likely outcomes. Further, we expect that such increases in price efficiency in the underlying securities markets would have some positive impact on capital formation and capital costs for the underlying entities, similar to the effect described above for re-proposed Rule 9j–1. As security-based swap prices become more informative, more likely reflecting the fundamental risk of the underlying entity, more market activity could follow.

Because of both the decreased counterparty risk and greater market integrity, the proposed Rule 10B–1 reporting requirements may also lead to lower litigation costs between security-based swap participants. As discussed above, the proposed rule would likely

limit or constrain exposure buildup in the security-based swap market, making it less profitable to accumulate positions at sizes that might incentivize market participants to affect the timing or the size payoff of the CDS contract. Although those actions may not be fraudulent, manipulative, or deceptive, there are situations (which are discussed in section I.B) where the accumulation of a large CDS position could signify misconduct. To the extent that an increased risk of litigation is associated with such potentially manipulative or unexpected behavior, proposed Rule 10B–1 would make it more likely that market participants can avoid such costs.

With respect to the requirements to report certain information,[233] public reporting of certain identifying information would have the benefit of increasing market liquidity, as a result of the counterparties being able to identify the market participant who exceeded the reporting threshold and limit their counterparty risk exposure to them.[234] In that regard, the use of standard identifiers—namely, the product ID for the security-based swaps, the FIGI for securities (or any other unique security identifier(s) that may be included at the filer's option), and the LEI for legal entities—on Schedule 10B would augment transparency by providing consistent identification of entities and securities across datasets and jurisdictions, allowing market participants to cross-reference the data reported on Schedule 10B with data reported from any other sources that use those standard identifiers.[235] In turn, enhanced transparency would reduce transactional and operational costs of trading, making transactions cheaper and more frequent.

Requiring the reporting of the notional amount of the applicable security-based swap, and related securities with the same underlying asset would allow market participants to quantify the size of the position in the security-based swap, the underlying security, and related securities, meaning that participants would know the exact size of the concentrated position that led to the threshold being exceeded. The information required to be reported by proposed Rule 10B–1 complements what is required to be reported pursuant to Regulation SBSR, and because market participants would, as a result of the proposed rule, be aware of counterparty risks, proposed Rule 10B–1 may encourage more participation in the market, which would increase liquidity in the market for security-based swaps.

In addition, as a second order effect, the proposed Rule 10B–1 could have positive spillover benefits in markets of the specific underlying entity, *i.e.,* bond markets for CDS and bond swaps, or equity markets for TRS, respectively. Specifically, the increased liquidity in the security-based swap market could allow participants in capital markets to more easily hedge capital investments they make in underlying entity securities (*e.g.,* both bond and equities). To the extent that capital investments are more easily hedged, capital market participants may be more likely to participate in these markets and hence more likely to provide capital to the underlying entities.

As discussed above, the Commission has access to single-name CDS data through DTCC–TIW and a subsample of TRS data through Form N–PORT.[236] In addition, reporting of security-based swap transactions is now required.[237] The Commission's oversight of the security-based swap market would be enhanced by the proposed reporting requirement in the proposed Rule 10B regarding related securities, which are not reported through DTCC–TIW or security-based swap transaction reporting. Proposed Rule 10B–1 would give the Commission access to information that would allow it to better evaluate a reporting firm's security-based swap positions (and in many cases, information about other securities positions), thereby allowing the Commission to identify potential market misconduct (*e.g.,* insider trading or market manipulation), default and contagion risk related to large concentrated positions.

Reporting entities would be required to file Schedule 10B on EDGAR in a structured, machine-readable data language (specifically, FIXML). This would benefit market participants by improving the usability, accessibility, and reliability of the Schedule 10B reports. By requiring a machine-readable language and a centralized, publicly accessible filing location for Schedule 10B, the Commission would enable market participants to download the reported information directly into their databases and analyze the information using various tools and applications, thus augmenting the informational benefits that Rule 10B–1 would create. The requirement to use FIXML, an open standard maintained by a market standard setting organization, for the Schedule 10B reports would allow those market participants that already use FIXML for financial information exchange to leverage their existing systems and processes in preparing the reports (if applicable) and/or using the reports for analysis. Use of FIXML may also allow greater comparability of the data to that from other reports to the Commission. Furthermore, because the EDGAR system provides basic validation capabilities, the requirement to submit Schedule 10B on EDGAR would reduce the incidence of non-discretionary errors of Schedule 10B, thereby improving the quality of Schedule 10B reports.

Concerning timing, proposed Rule 10B–1 would require security-based swap entities to file promptly, but in no event later than the end of the first business day following the day of execution of the security-based swap transaction that results in the exposure exceeding the reporting threshold. The benefit of filing promptly would likely lead to increases in market and price efficiency as prices would reflect this information quickly. That is, counterparties would be able to react quickly if warranted to this additional information by adjusting their security-based swap, underlying security, or related security positions, or margin requirements.

ii. Costs

The Commission expects Rule 10B–1 to create reporting costs for counterparties that have large concentrated exposures that breach the reporting thresholds, and decrease liquidity or increase trading costs for

[233] *See* proposed Rule 10B–1(a) and Schedule 10B (providing a complete list of information required to be disclosed). Proposed Rule 10B–1 would require persons subject to the proposed rule to report, among other things: (1) Identifying information, including for example, the name of reporting party, the reporting party's LEI and the LEIs of the issuers of underlying and related securities (if available), place of organization, type of reporting person; and (2) the notional amount of the applicable related security-based swap, the underlying security's FIGI, and the FIGIs of related securities that share the same underlying asset.

[234] Having a reporting requirement with no identification might only partially solve the informational asymmetry problem described in the Basic Economic Considerations section. For example, if the report was designed to only disclose information about the security-based swap and underlying securities, but withheld information about the security-based swap participant, it would potentially lead to all market participants to believe their particular counterparty was the one that breached the threshold. The missing information would likely cause market participants to unnecessarily withdraw from the market, decreasing either supply or demand.

[235] Product IDs, if available, are a required element of security-based swap reporting obligations under Regulation SBSR. *See* 17 CFR 242.901(c)(1). Regulation SBSR reporting obligations do not require LEI or FIGI.

[236] *See supra* section VI.C.2 (describing security-based swap data).

[237] *See supra* section VI.C.1 (describing existing major regulatory reporting regimes for security-based swap market).

entities who have triggered reporting thresholds. As discussed above, to the extent that market participants are better able to assess counterparty risk as a result of the reporting that would be required under proposed Rule 10B–1, market participants may limit their security-based swap activity with counterparties who have triggered the proposed rule's reporting thresholds. A market participant may determine that a counterparty that has triggered the reporting thresholds is too risky to trade with, or may increase initial or variation margins. While we believe that, as discussed above, liquidity for the overall market would improve as a result of the proposed rule, we believe that this the rule could decrease liquidity for these particular market participants.

Proposed Rule 10B–1 would impose reporting costs on market participants who trigger the proposed rule's thresholds. The Commission estimates that the number of reports would generally be less than 136 reports per week for U.S. security-based swap participants in the single-name CDS market.[238] The Commission expects this number to represent an upper limit for reports, as it is possible that some CDS counterparties would refrain to some extent from acquiring exposures that would require reporting. Additionally, the Commission expects the number of reports related to TRS positions to be smaller than the number of reports related to CDS positions, although the Commission cannot yet estimate a precise number due to the data limitations discussed above.[239] Some market participants are already subject to the reporting obligations of Regulation SBSR or SDR or Section 30(b) and Rule 30b1–9 of the Investment Company Act of 1940, so these entities may have already made previous relevant expenditures to build a technology system for reporting. Nonetheless, the monitoring of positions and, to the extent thresholds are triggered, public reporting of positions represents an additional reporting expense for all market participants, some of whom may not be familiar with reporting to the Commission.

As discussed above, up to 850 respondents will likely need to develop a technological infrastructure to calculate and monitor their security-based swap positions, even if some of those entities do not have at least one Security-Based Swap Position that is required to be reported pursuant to proposed Rule 10B–1(a).[240] We estimate that each respondent will incur a one-time initial cost of approximately $101,740 to develop such technological infrastructure, or $86,479,000 in the aggregate for all 850 respondents. In addition to developing the technological infrastructure to calculate and monitor their Security-Based Swap Positions in order to comply with the requirements of proposed Rule 10B–1, each respondent will be required to maintain and operate such system on an ongoing basis. The Commission estimates such annual costs will be $77,000 per respondent, or $65,450,000 in the aggregate for all 850 respondents. In addition to maintaining and operating such technological infrastructure, the Commission also believes that each respondent will incur a $1,000 annual cost to store such security-based swap position data, or $850,000 in the aggregate for all 850 respondents.

In addition, to the extent that market participants are better able to assess counterparty risk as a result of the reporting that would be required under proposed Rule 10B–1, market participants may limit their security-based swap activity with counterparties who have triggered the proposed rules' reporting thresholds. Where a counterparty has triggered reporting thresholds, the market participant may determine that the party is too risky to trade with, or may increase initial or variation margins. Under these circumstances, market participants may not trade with a reporting counterparty, trade only at prices that account for additional risk, or ask for larger margin postings of collateral.

As discussed above, proposed Rule 10B–1 would require persons subject to the proposed rule to report, among other things, identifying information, the notional amount of the applicable security-based swap (and in the case of equity-based security-based swaps, the percentage of shares represented by the security-based swap as a percentage of the outstanding number of shares), and related securities. The requirement to report information that identifies the market participant, for example the LEI, would allow market participants to identify the security-based swap participant that breached the threshold. With respect to the LEI requirement in particular, the Commission does not expect the requirement would impose compliance costs on reporting persons, because reporting persons would only have to provide LEIs only if they possess one at the time of submitting the report, and thus would not have to incur the cost to obtain and renew an LEI for the purpose of filing Schedule 10B.[241]

Other components of the reporting requirements would be costly to market participants because these reports could make their trading strategies public (by virtue of disclosing the size of their position), potentially causing their strategy to be less profitable in the future. For example, this information might lead other parties to replicate and use the reporting party's trading strategy for their own purpose. However, the information provided would be limited to only security-based swaps and related securities, and would not include information about the reporting parties' entire portfolios.

The requirement to file Schedule 10B reports on EDGAR would impose upon those reporting parties without prior access to EDGAR a one-time compliance burden of submitting a Form ID as required by Rule 10(b) of Regulation S–T and following the processes detailed in Volume I of the EDGAR Filer Manual. The FIXML data language requirement for Schedule 10B would not impose additional incremental compliance costs on reporting parties, because any reporting party without experience or expertise surrounding FIXML could choose to input its Schedule 10B reports in a fillable online form, rather than submit its reports directly in the FIXML data language. Filers who choose the

[238] The Commission estimates, at most, approximately, 136 reports per week (79 as a result of net threshold breaches, and 57 as a result of gross thresholds breaches) related to single-name thresholds. The analysis is based on DTCC–TIW data, which uses weekly holdings of single-name. *See infra* section VI.D.2.iii.(A).

[239] The Commission believes that the market for TRS is smaller than the market for CDS, and the CDS single name market is the representative market for security-based swaps in general, hence the Commission expects fewer reports from TRS compared to single-name CDS.

[240] *See supra* section V (quantifying a subset of the costs associated with proposed Rule 10B–1—specifically, the burden of information collection costs estimated for the purposes of the Paperwork Reduction Act).

[241] Should a reporting entity choose to obtain an LEI, the initial and renewal fees would vary based on the home jurisdiction of the reporting entity. *See https://www.gleif.org/en/about-lei/get-an-lei-find-lei-issuing-organizations.* A U.S. entity can obtain for a one-time fee of $65 and an annual maintenance fee of $50 per year. *See, e.g., https://lei.bloomberg.com/docs/faq#what-fees-are-involved.* Prices were retrieved from Bloomberg Finance, L.P., one of twelve LEI Operating Units that are accredited to issue LEIs to U.S. entities. Similarly, the other standard identifier requirements (FIGI for securities and product ID for security-based swaps) are not expected to result in compliance costs for reporting persons. FIGIs are automatically assigned and are retrievable and redistributable at no cost. Product IDs are required to be reported for all security-based swap transactions per Rule 901 of Regulation SBSR, so a reporting person would not incur any incremental cost associated with obtaining a product ID for the purposes of Schedule 10B. *See* 17 CFR 242.901(c)(1).

submit the required Schedule 10B reports directly in FIXML rather than use the online form, and who do not have experience structuring data in FIXML, would incur incremental implementation costs associated with developing the necessary expertise and establishing the necessary compliance processes (*e.g.,* encoding and maintaining the required data in FIXML and transmitting the data to EDGAR) to comply with the FIXML requirement. For those filers, and for other filers choosing to submit Schedule 10B reports directly in FIXML, the Commission expects that the automated processing enabled by the structured data requirement would make subsequent compliance costs lower than the compliance costs of manually inputting Schedule 10B reporting into the web form with each submission.

With respect to timing, proposed Rule 10B–1 would require security-based swap entities to file promptly but in no event later than the end of the first business day following the day of execution of the security-based swap transaction that results in the security-based swap exposure exceeding the reporting threshold. The cost of filing no later than the end of the first business day following the day of execution of the security-based swap transaction would likely not require the reporting party to invest in new IT infrastructure and automation. As discussed above, the Commission estimates 136 reports from U.S. entities per week in the single-name CDS market.[242]

In addition, proposed Rule 10B–1 may impact how security-based swap transactions take place across national borders. As discussed above, the reporting requirements of proposed Rule 10B–1 would be based on the reporting and public dissemination requirements in Regulation SBSR and, in addition, apply under certain circumstances when the reporting person holds any amount of reference securities underlying the Security-Based Swap Position (or would be deemed to be the beneficial owner of such reference securities, pursuant to Section 13(d) of the Exchange Act and the rules and regulations thereunder). This could place reporting persons at a disadvantage compared to non-reporting ones. U.S. security-based swap market participants and some foreign entities that would be required to report would be at a disadvantage, because they would be required to comply with proposed 10B–1 while some foreign participants would not be required to comply, while they would be able to access the publicly available reports required by proposed Rule 10B–1. As a result, a portion of reporting entities for whom these reporting costs are large might be incentivized to change their geographical location of operation to a non-U.S. jurisdiction and limit their participation in the underlying securities' markets. On the other hand, proposed Rule 10B–1 would likely increase the trading of non-reporting U.S. persons, as these thresholds would not affect them while providing them with additional transparency and reporting in the security-based swap market. Because of lower counterparty risk and improved market conditions, non-reporting U.S. persons may become more active in the security-based swap market.

iii. Reporting Thresholds

The costs and benefits of proposed Rule 10B–1 are dependent, in part, on which parties would be subject to the reporting requirements, as determined by the selected thresholds for each type of security-based swap. As a general matter, a higher threshold will lead to fewer reports. This may limit the benefits of the proposed rule, but decrease both the direct compliance costs and costs that investors face, as discussed above, when revealing information to the market that they consider material. In other words, a higher threshold would likely decrease reporting costs, but higher thresholds would resolve fewer of the asymmetric information scenarios that amplify the market imperfection. Similarly, a lower threshold, with more reports, may increase benefits associated with the proposed rule, but increase costs. We discuss below the expected number of affected parties at various thresholds, including the thresholds proposed in the rule.

(A) Thresholds for Credit Default Swaps

For single-name CDS and for narrow index-based CDS, the Commission has identified the threshold as the lesser of: (i) A long notional amount of $150 million, calculated by subtracting the notional amount of any long positions in a deliverable debt security underlying a security-based swap included in the CDS from the long notional amount of the CDS (the ''$150 million long threshold''); (ii) a short notional amount of $150 million; or (iii) a gross notional amount of $300 million. Calculations for the short notional amount threshold of $150 million would not add or subtract the notional amount of any positions in a deliverable underlying debt security, and calculations for the both the long and short $150 million notional amount thresholds would not net out any other Security Based Swap. In addition, persons who have previously filed a Schedule 10B with the Commission would be required to file amendments if any material change occurs in the facts set forth in a previously filed Schedule 10B including, but not limited to, acquisitions in an amount equal to 10% or more of the position previously reported in Schedule 10B.

Reporting following a trigger of the $150 million long or short threshold would inform the Commission, market participants, and the public in general about market positions with large potential market impact, which could lead to significant reduction of asymmetric information when reported. Further, the calculation method for the $150 million long threshold would limit reporting and reporting costs by excluding deliverable bonds, and help market participants identify situations where a counterparty has a higher likelihood of having incentives to undertake opportunistic trading strategies. However, at larger notional amounts, quickly converting to a long position potentially netted by deliverable bonds to only a long gross positon presents additional risk;[243] accordingly, the Commission is proposing a second larger threshold, $300 million notional on a gross basis, to capture overall large exposures.[244] By knowing that a counterparty has a large gross notional amount and is directionally[245] neutral, the party could accordingly adjust its price expectations and margin requirement of trading with that counterparty. This adjustment would account for the risk associated with trading with a counterparty that could quickly transform its directionally

[242] *See supra* section VI.D.2.iii (disclosure thresholds) on discussion related to how the Commission estimated the number of reports for single-name CDS market.

[243] For example, a market participant may hold a large gross position that is net neutral (non-directional), just below the gross reporting threshold and not be required to file Schedule 10B. Thereafter, the participant quickly converts the gross position to a directional position by offloading the more liquid side of the trade, thus quickly converting the net neutral to a large directional position.

[244] The Commission believes that these thresholds, together with those described below for non-CDS debt security-based swaps and security-based swaps on equity, would likely have triggered position reporting under circumstances similar to those described above with respect to observed instances of ''opportunistic strategies'' and scenarios of high counterparty risk. *See supra* section I.B.

[245] Directional positions are holdings where market participants are not net neutral (*i.e.,* their long and short positions do not net out) because said participants have an expectation about the future movement of an asset and expect to profit from the risk taken with the position.

neutral position to one directional in nature.

These thresholds limit the number of reporting parties that would be required to report and the related costs (including related to compliance and analyzing this information), while still addressing the market failure as a result of the adverse selection caused by asymmetric information in the market. For example, if the thresholds were lower the Commission would expect a larger number of reports, likely more uninformative ones with not sizable exposure, while increasing the burden to understand the reports, limiting the benefit of the overall reporting.

The Commission used single-name CDS positions data from DTCC–TIW to estimate: (a) The number of market counterparties in the CDS market affected by proposed Rule 10B–1 for various thresholds; (b) the number of initial reports that would likely need to be filed on a weekly basis for various thresholds, as well as the number or amendments that might as a result of material changes; and (c) the percent of market participants that would be required to file no reports per week, (0–10) reports per week, [10–20) reports per week, or more than 20 reports per week, based on data from January 1, 2020 to December 31, 2020.[246] We discuss these estimates in detail below.

Estimate of the Number of Market Counterparties in the CDS Market Affected by Proposed Rule 10B–1

To understand the number of market counterparties in the CDS market affected by proposed Rule 10B–1 at potentially different threshold levels, the Commission calculated concentration statistics for the year 2020, as shown in Figure 2 below. To perform this estimate, the Commission calculated the number of parties that might be impacted at different long/short notional amounts and gross thresholds represented with seven buckets: [0–50), [50–100), [100–150), [150–200), [200–250), [250–300), and [300+) in millions of US dollars. Each bucket represents the percent of accounts with exposure in a week for at least one underlying entity.[247]

Figure 2: Global distribution of notional trading volume[248] in North American corporate single-name CDS, and U.S. entities' accounts in any single-name CDS, year 2020

As shown in Figure 2 (left), roughly 88% of accounts—hold a position larger than the short notional exposure of $150 million, and less than the long net exposure of $150 million. 5% of accounts have a position larger short position than the $150 million short notional exposure, while 7% of accounts have a larger long position than the $150 million long notional exposure. This estimate for accounts affected by the long dollar exposure threshold is an upper bound, as it does not account for offsetting holdings in the deliverable bonds. [249] The Commission does not have access to granular data on bond holdings and so cannot compute the net positions if these positions were hedged by deliverable bonds. Hence, the Commission expects that fewer than 12% (5% from short positions larger than $150 million, and 7% from long positions larger than $150 million) of market participants would be impacted by the reporting requirements in proposed Rule 10B–1, as a result of the $150 million notional amount threshold for both long and short positions. Similarly, only 9% of accounts on average hold a gross exposure on a single name underlying entity of more than $300 million, the last of the thresholds, [300, +).

Further, to understand the size and jurisdiction of underlying entities referenced by single-name CDS, Commission staff performed additional

[246] For specific notation, the following bucket, [0–50), means that 0 is included in this bucket, while 50 is not included in the bucket.

[247] DTCC–TIW includes weekly CDS positions for all U.S. entities, or foreign counterparties to a U.S. entity, or foreign counterparties trading CDS referencing a U.S. underlying entity. By aggregating available position information, the Commission is able to calculate exposure.

[248] A long notional exposure is indicated with positive values, while a short notional exposure is indicated with negative values.

[249] Bonds of the underlying entity that are delivered in the auction are a subset of all underlying referenced debt that the underlying entity may have. This subset more closely tracks the value of the CDS as only those bonds would determine the final recovery value and the CDS payoff. *See, e.g.,* the Big Bang protocol: *https://www.cdsdeterminationscommittees.org/companies/auctionhardwiring/auctionhardwiring.html.*

analysis using the DTCC–TIW data. The left chart shows the size distribution of US firms. Most US firms that have a referencing CDS are large, with 57% of them having an average of $10 billion or more in total book value of assets at the end of year from 2009 to 2020.[250] The right chart shows the country distribution of single-name CDS reported in DTCC–TIW. 33% are underlying entities referenced in the US, followed by approximately 22% in the European Union.

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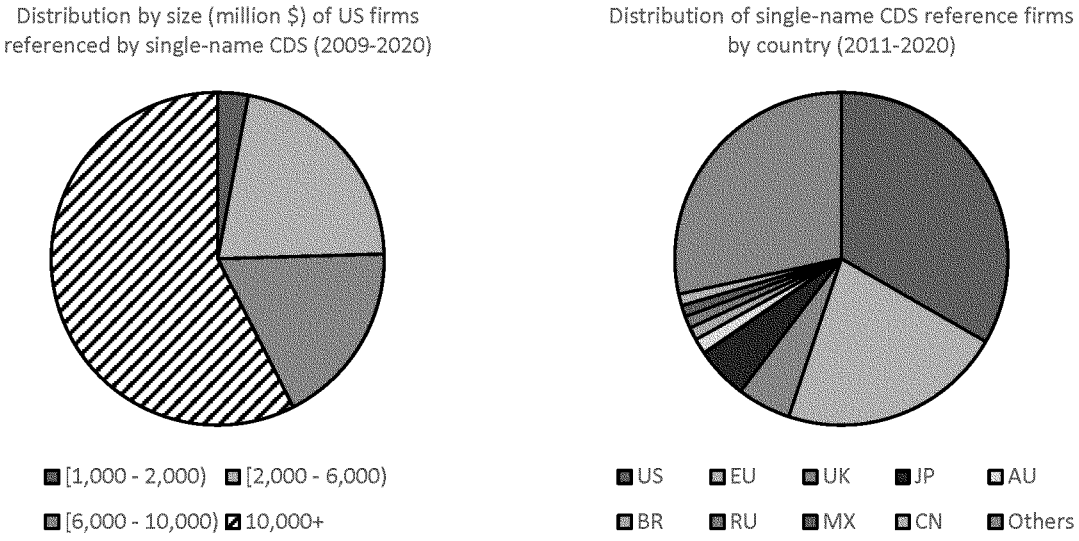
Figure 3: The distributions of the size of US firms referenced by single-name CDS (left) and the jurisdictions of firms referenced by single-name CDS as reported by DTCC-TIW (right)



Estimate of the number of reports to be filed on a weekly basis

Commission staff used single-name CDS positions data from DTCC–TIW to evaluate the number of initial reporting that would likely need to be filed on a weekly basis, as well as the number of amendments that may need to be filed because of the requirement to file amendments in connection with material changes. Commission staff performed this analysis on two samples. The first sample, shown in Figure 4, uses all exposures on single name North-American CDS underlying entities and all exposures of U.S. single-name CDS participants. The second sample, shown in Figure 5, narrows the analysis to only U.S. single-name CDS participants (counterparties), and does not consider foreign single-name counterparties who have exposure to North-American CDS.[251] This is a subset of the DTCC–TIW data, which includes U.S. counterparties in the single-name CDS market, and covers both U.S. counterparties' North American and foreign underlying entities CDS holdings. The left charts in Figure 4 and Figure 5 show the number of reports the Commission expects to receive weekly (y-axis) for each sample across various long/short thresholds (x-axis) and for different material percent changes, represented by different lines in the chart. The black line represents the threshold levels selected by the Commission.

[250] This value represents the average end of year book value for each firm, as reported in Compustat. Similar statistics regarding the size of the single-name CDS are reported in Lee, Naranjo, and Velioglu, *supra* note 229 at 556–78.

[251] Commission staff considered all DTCC–TIW entities' aggregate weekly holdings across accounts all single-name CDS in 2020, for 52 weeks. Commission staff then assumed that the proposed reporting requirements from proposed Rule 10B–1 were implemented from the first week of 2020. For entities on an aggregate level, Commission staff then assessed the number of reports different potential reporting thresholds and weekly material changes would have. The analysis then aggregates the number of triggers for each firm's entire single-name CDS positions in 2020 across 52 weeks. For example, Figure 5, considers the following reporting net (left plot) and gross (right plot) thresholds listed on the x-axis: $50 million, $100 million, $150 million, $200 million, $250 million, $300 million and $500 million and material percentage change (lines at 1%, 5%, 10%, 20%, and 30%).

Figure 4: Expected number of reports by global security-based swap participants' exposure to North American single-name CDS and U.S. security-based swap participants' exposure to single-name CDS across long/short and gross thresholds

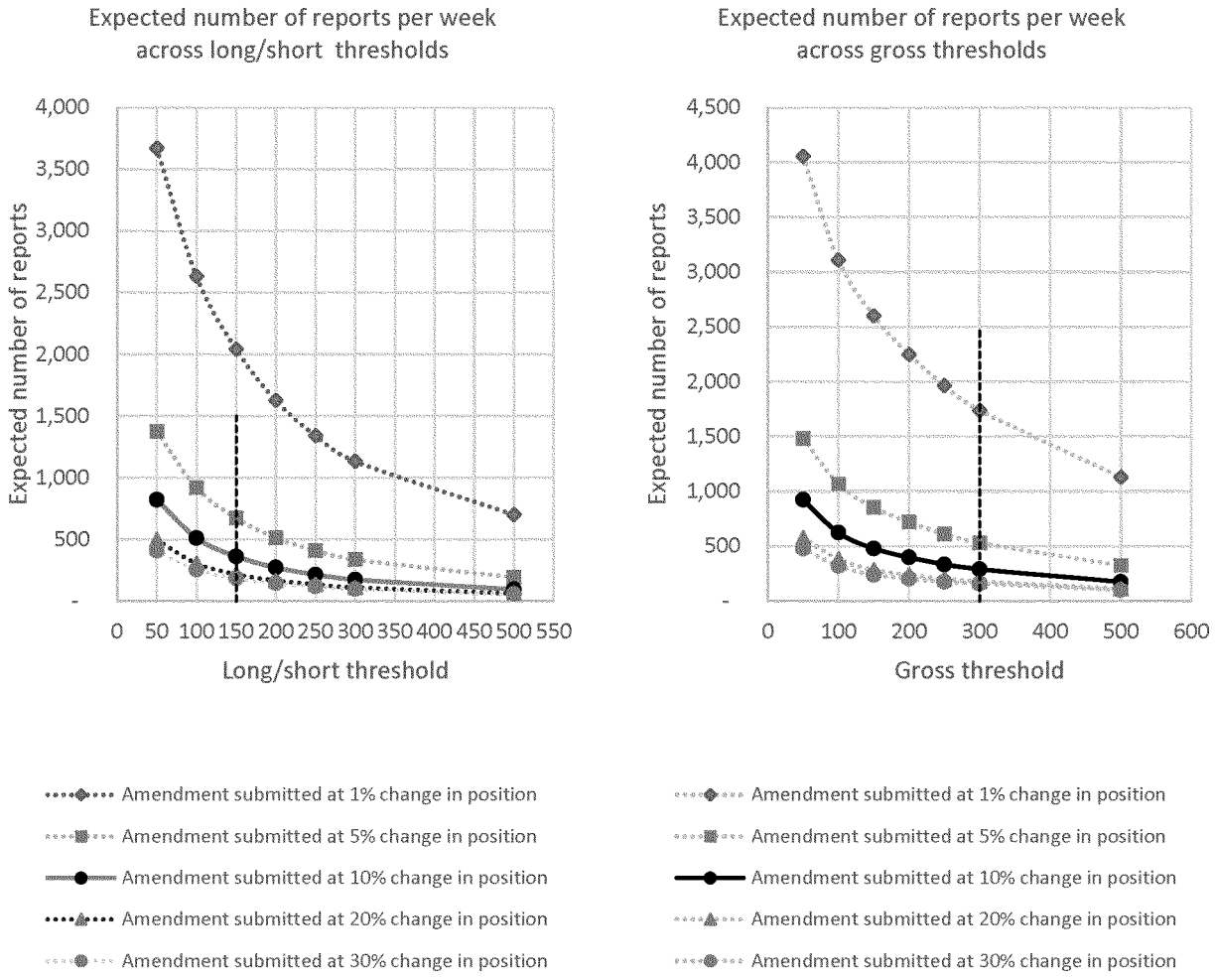
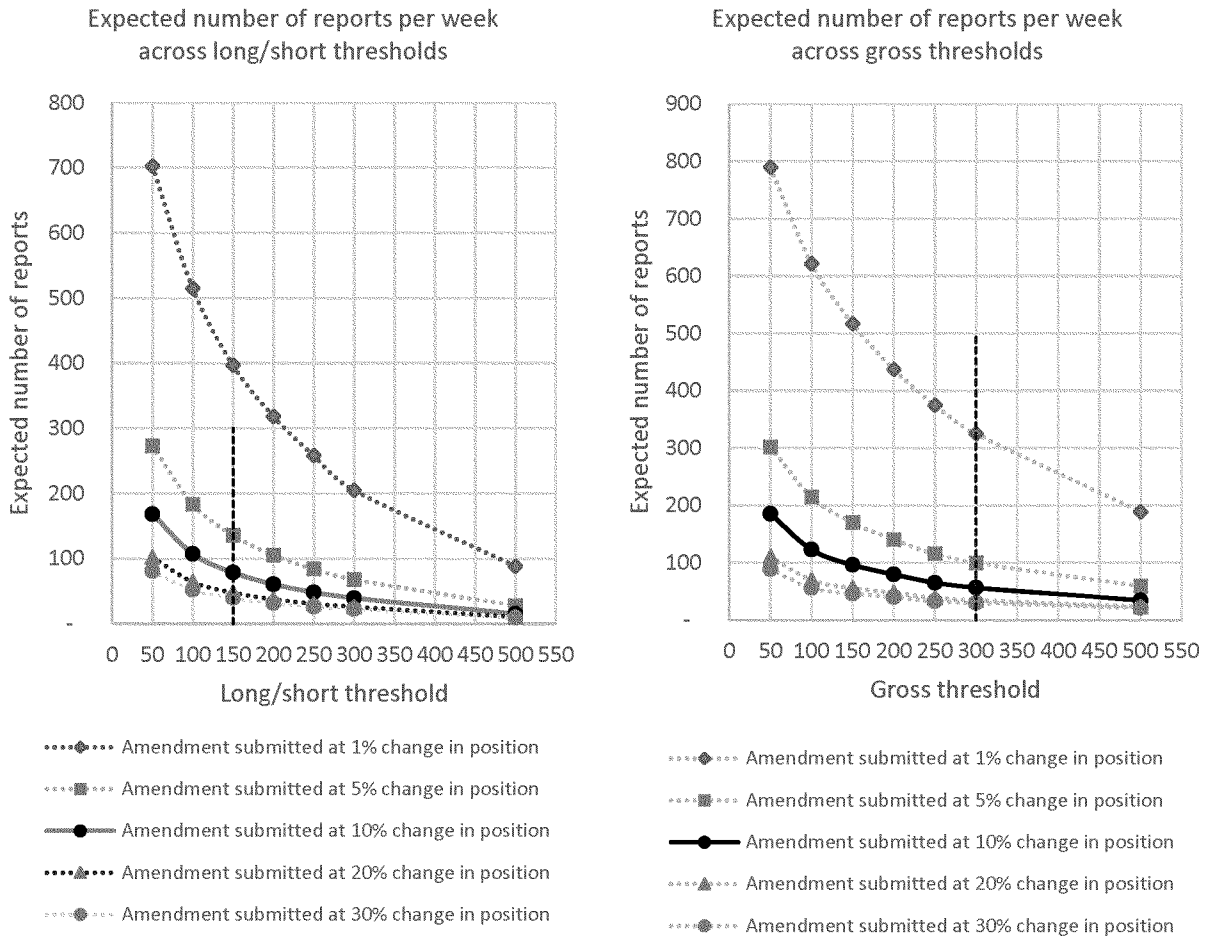


Figure 5: Expected number of reports by U.S. security-based swap participants across long/short and gross thresholds



The left chart in Figure 5 shows that the Commission expects slightly more than 79 reports per week as a result of U.S. entities triggering the long/short proposed thresholds of $150 million with a material percent change threshold of 10%, as it relates to CDS. Similarly, the right chart in Figure 5 represents the number of reports the Commission expects to receive weekly from U.S. entities across gross thresholds (x-axis) and different material percent changes. The right chart in Figure 5 shows that the Commission expects an additional 57 reports per week as a result of U.S. entities exceeding the gross proposed threshold of $300 million with a percent change of 10%. In total, the Commission expects at most 136 reports per week from U.S. entities with respect to CDS positions, 79 reports as a result of the long/short thresholds and 57 reports as a result of the gross threshold.[252]

These estimates are upper bounds for U.S. entities because Commission staff cannot net out deliverable bonds due to limited data. Such data limitations relate to the bond holdings of security-based swap participants that would be eligible to offset the net positions and that would decrease the single-name net exposure. In addition, the proposal would require reporting by the party with the swap exposure (*e.g.,* a pension fund or industrial company, but not the investment adviser who trades on behalf of this party). Because Commission staff analysis is at the level of entities in Table 1, which pools exposures of the underlying parties, the analysis overestimates the right-skewness of the distribution of exposures, and hence overestimates the number of entities reporting. As a result, this methodology correctly captures entities that might directly report to DTCC–TIW across several of their individual accounts, as the methodology captures the entities' aggregate exposure. Parallel to this, the methodology overestimates the size of the holdings of parties that act as dealers in the single-name CDS market because it aggregates the accounts of market participants that are reported to DTCC–TIW as being held by the dealer. In addition, Commission staff only observed end-of-week exposures, hence intra-weekly changes in position that might breach these thresholds were not accounted for. There are a limited

[252] In addition to these 136 reports, the Commission also expects a number of foreign entities to report based on a similar analysis using DTCC–TIW data. Including foreign entities, the Commission believes that there will be is a total of 362 reports a week as a result of the net threshold, 79 reports from U.S. entities and 283 from foreign entities. If the gross threshold is used, the Commission estimates 291 reports a week, including 57 reports from U.S. entities and 234 reports from foreign entities. The Commission believes that these numbers may be overestimated because: (i) Only foreign entities that hold underlying U.S. securities would need to report; (ii) the Commission's analysis considers aggregate holdings across all accounts, hence this methodology correctly captures entities that might directly report to DTCC–TIW across several account, but overestimates the size of holdings of parties that directly report to DTCC–TIW, but while acting as dealers in the single-name CDS market by having accounts other participants; and (iii) there may be entities that trigger both thresholds simultaneously (*e.g.,* if an entity hold as a gross position of $300 million with a net position of $150 million) so those entities would be double counted in these figures.

number of such dynamic intra-weekly changes in positions, as participants are more likely to hold longer-term swaps positions.[253] In addition, the analysis does not account for reports that might be filed as a result of an entity triggering both long/short and gross threshold breaches in the same week. For example, a large long or short position and a large gross position happening contemporaneously would be counted twice in the estimation (once in each sample). These overestimations, for the number of U.S. entities and for all reporting parties in DTCC–TIW, lead the Commission to believe that the estimated number of weekly reports are likely overestimated, and the Commission expects significantly fewer reports per week in practice.

Estimate of the Percent of Market Participants That Would be Required To File Certain Numbers of Reports

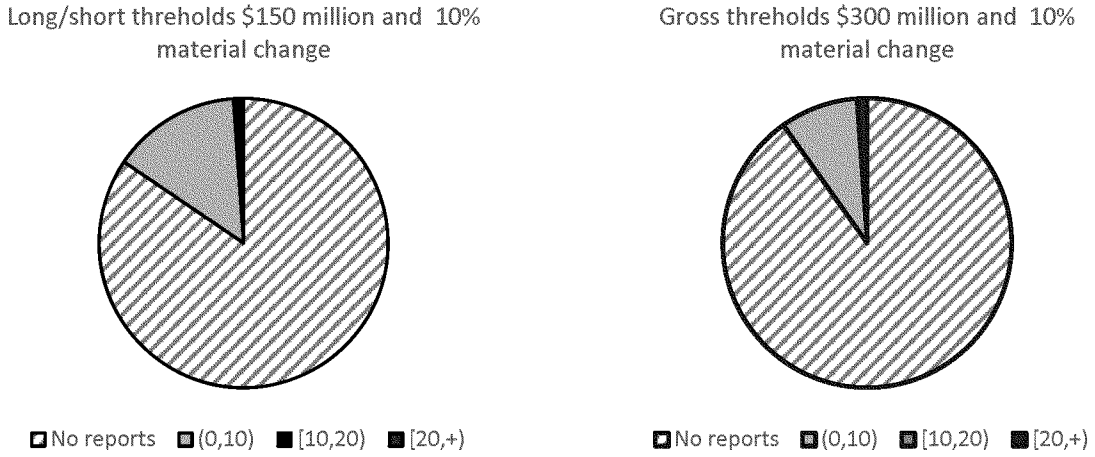
In Figure 6 below, using DTCC–TIW data, the Commission estimated the percent of market participants that would be required to file reports based on data as of January 1, 2020. Specifically, the analysis breaks down how many participants would file, on average, no reports per week, (0–10) reports per week, [10–20) reports per week, or more than 20 reports per week.[254] Figure 6, is based on global security-based swap participants with exposure to North American single-name CDS and U.S. security-based swap participants with exposure to any single-name CDS. Because Figure 6 includes all available positions in the DTCC–TIW data (including some positions of foreign entities not trading securities referencing U.S. entities, who would not be required to report under the proposed rule), this analysis likely overestimates the percent of the market participants required to report. The Commission has, therefore, provided a second estimate in Figure 7, below, which represents only U.S. security-based swap participants' exposure to any single-name CDS. The Commission expects that many reports will be filed by SBSDs because, as liquidity providers, they will likely interact with clients executing large positions in CDS or TRS, and further, SBSDs are likely to hedge these positions.

Figure 6: Percent of Global security-based swap participants with exposure to North American single-name CDS or U.S. security-based swap entities with exposure to single-name CDS that would have filed weekly reporting in 2020.[a]

[a] The Commission lacks data on specific foreign entity holding of U.S. bonds. As a result, this analysis does not account for foreign entities with no ownership of the underlying security that might be required to report in certain circumstances and that are in upper bounds for the number of expected reports from foreign entities.

[254] The following bucket, (0–10), means that neither 0 nor 10 are included in this bucket.

Figure 7: Percent of U.S. entities with exposure to single-name CDS that would have filed weekly reporting in 2020.



As shown in the left chart in Figure 6, the Commission estimates that 22% of global security-based swap participants with exposure to North American single name CDS and U.S. entities with exposure to single-name CDS would be required to file, on average, fewer than 10 reports per week as a result of reaching the $150 million long/short thresholds and the 10% change in position that would require the filing of an amendment. Furthermore, the Commission estimates that only 1% of global participants in the security-based swap market with exposure to North American single name CDS and U.S. entities with exposure to single name CDS would be required to file more than 20 initial reports or amendments on average in a week as a result of the $150 million threshold. Similar estimates are shown for U.S. entities alone in Figure 7, with a cumulative 99% of U.S. entities filling less than 10 initial reports or amendments on average a week. Likewise, only 1% of U.S. single-name CDS market participants would need to file more than 10 initial reports or amendments per week on average. Similar to previous estimates, long/short threshold estimates presented in Figures 6 and 7 are conservative upper bound estimates, as the Commission cannot adjust for bond positions that would offset the size of the CDS holdings, as well as aggregate positions that might be reported in DTCC–TIW across one or many different dealers.

Commission staff performed a similar analysis for the gross threshold at $300 million for both groups of participants. As shown in Figure 7, the Commission estimates that 90% of U.S. single-name CDS market participants will, on average, not be required to file any reports under the proposed Rule 10B–1 for the gross threshold, while if required to file, 9% of U.S. single-name CDS participants would be required to file fewer than 10 reports on an average week, and only 1% of U.S. security-based swap market participants would be required to file more than 20 initial reports or amendments per week on average.[255]

(B) Thresholds for Non-CDS Debt Security-Based Swaps and Security-Based Swaps on Equity

As discussed above, the Commission is proposing: (i) For security-based swaps based on equity, a bifurcated approach, such that a reporting obligation would be triggered by exceeding the lesser of a threshold based on the notional amount of the Security-Based Swap Position, and a threshold based on the total number of shares attributable to the Security-Based Swap Position as a percentage of the outstanding number of shares of that class of equity securities and (ii) for other non-CDS debt security-based swaps, a notional based threshold approach. In addition, persons who have previously filed a Schedule 10B with the Commission would be required to file amendments if any material change occurs in the facts set forth in a previously filed Schedule 10B including, but not limited to, acquisitions in an amount equal to 10% or more of the position previously reported in Schedule 10B.

The Commission believes that these thresholds achieve the goal of informing the market and the public about impactful and directional positions in TRS, which could lead to significant reduction of asymmetric information when reported. The notional thresholds of $300 million (which includes not only the TRS or other equity security-based swaps and related securities) of which $150 million (which includes only the TRS or other equity security-based swaps) provides a bright-line, absolute measure of position size and is similar to the approach proposed for CDS. The bright-line provides a simple and specific reporting threshold for participants. We are also proposing a threshold based on the total number of shares attributable to the Security-Based Swap Position as a percentage of the outstanding number of shares of that class of equity securities. The 5% threshold relative to market capitalization (out of which 2.5% are in TRS and equity security-based swaps) is required because there are a large number of firms in the market that would not be captured by the notional thresholds, which the Commission believes should be captured in order to reduce asymmetric information problems in the TRS market. Based on the Commission's analysis, smaller underlying entities make up a significant portion of the U.S. firms referenced by TRS. For smaller underlying entities to be adequately captured and thereby effectively to reduce asymmetric information in the market for swaps referencing their securities, the Commission believes a percentage threshold is required. This is demonstrated in Figure 7.

In evaluating the effect of these thresholds, the Commission used data from Form N–PORT filings, which include information on holdings of, among other things, security-based swaps, to (a) estimate the number of

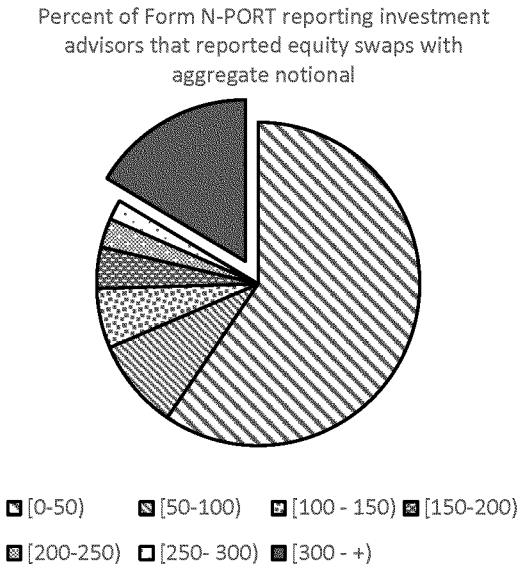
[255] The analysis has a similar limitation as noted above in ''Estimate of the number of reports to be filed on a weekly basis.''

market counterparties affected by proposed Rule 10B–1's notional thresholds for non-CDS debt security-based swaps and security-based swaps on equity and (b) analyze the size and jurisdiction of underlying entities referenced by total return, equity, and other non-CDS, debt security-based swaps. We discuss these analyses in detail below.

Estimate of the Number of Market Counterparties in the Market for Non-CDS Debt Security-Based Swaps and Security-Based Swaps on Equity Affected by Proposed Rule 10B–1

Using data from each fund's [256] latest Form N–PORT filing as of November 15, 2021, Commission staff estimated the percent of accounts with TRS aggregate positions within certain buckets of notional size, where each bucket represents the percent of accounts with TRS aggregate positions within the corresponding notional size. For example, 84% of funds reporting on Form N–PORT hold an aggregate position of $300 million or less in TRS, while 16% of these funds have an aggregate position to TRS of $300 million or more.

Figure 8: Aggregate Positions based on each fund's latest Form N-PORT filling as of November 15, 2021



Numerical depiction of the right skewed distribution of

Form N-PORT funds

Form N-PORT fund statistics	
25th percentile	$24 thousand
50th percentile	$131 thousand
75th percentile	$713 thousand
Average	$10.6 million

In addition, based on data from each fund's latest Form N–PORT filing as of November 15, 2021, the Commission provides several relevant summary statistics: First, there are 21,211 TRS being reported across 652 funds from Form N–PORT fillings; second, the median size of aggregate TRS positions of N–PORT reporting filers' funds is $131,000, while the average size is $10.6 million. These summary statistics imply that the TRS holdings of N–PORT-reporting filers' funds are right-skewed [257] and that these entities in aggregate hold a very limited position in total returns swaps. Lastly, the 25th and 75th percentiles are $24,000 and $713,000, which implies that 75% of N–PORT reporting filers' funds participate in the TRS market hold less than $713,000 in these products.[258] Based on the distribution demonstrated by this analysis, the Commission believes only a limited number of N–PORT filers' funds would be exceed the 10B–1 reporting requirement.[259]

Evaluation of Size and Jurisdiction of Underlying Entities Referenced by Total Return, Equity, and Other Non-CDS, Debt Security-Based Swaps

[256] For purposes of this discussion, ''funds'' are series of registered investment companies or registered investment companies if there are no series.

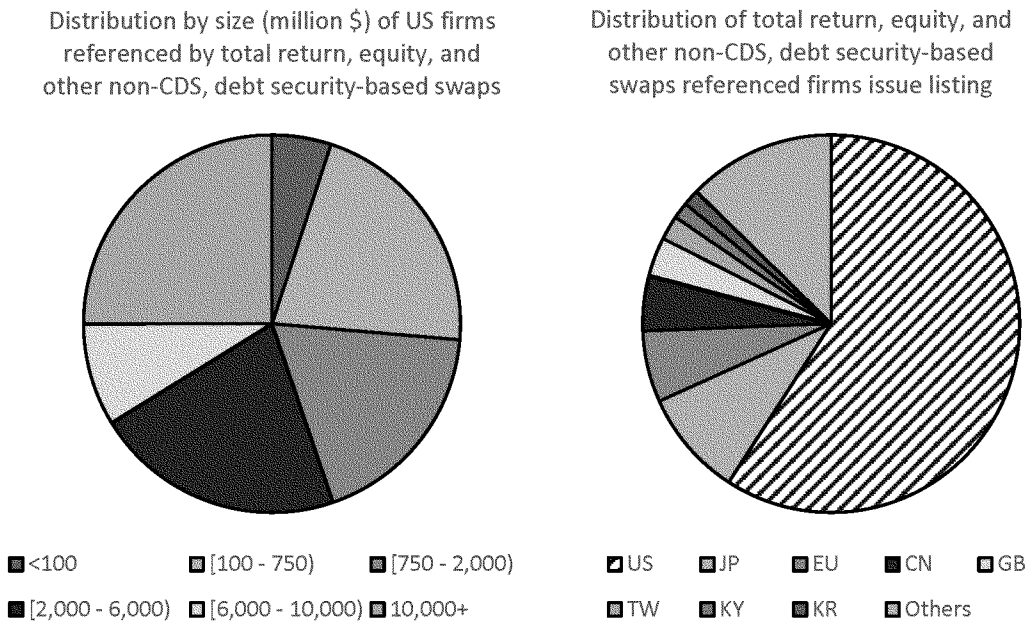
[257] A ''right-skewed'' distribution is one in which the tail is on the right side, and typically the mean (average) is greater than the median.

[258] Due to data limitations, the Commission's analysis does not separate the analysis into individual types of TRS.

[259] The Commission recognizes that Form N–PORT reporting filers may not be representative of the ''average'' trading entity in the security-based swap market and in particular, the ''average'' trading entity in the total return, or equity swap market. The Commission believes that Form N–PORT-reporting investment funds are likely to be less leveraged and participate in a smaller number of transactions compared to other entities that participate TRS market. *See generally* 17 CFR 270.18f-4 (''Rule 18f-4'') (limiting the ability of registered investment companies and business development companies to engage in transactions that involve potential future payment obligations, including obligations under derivatives such as forwards, futures, swaps and written options). Hence, the quantitative analysis provided on TRS using Form N–PORT reporting entities is likely to be biased towards TRS market participants that are more risk averse, less active in the TRS market, and more likely to currently be subject to reporting requirements and leverage limitations. This will result in estimates that would likely suggest a lower bound on the number of potential entities subject to the Rule 10B–1 disclosure requirement. In addition, due to data constraints, offsetting positions are not being reflected in this analysis. This would mean that the ''average'' TRS market participant is likely to be more active, less risk averse, and likely have larger exposures and positions in the TRS market. Despite the Commission's current data constraints regarding TRS, the Commission believes that these data provide useful market insight into the number of participants in the TRS market that might be impacted by the new reporting requirements. Certain information on Form N–PORT is non-public, while certain information reported on Form N–PORT for the third month of each filer's fiscal quarter is made publicly available upon filing.

Commission staff also analyzed the size and jurisdiction of underlying entities referenced by TRS, equity security-based swaps, and other non-CDS, debt security-based swaps. In Figure 9, the Commission performed a name matching procedure across Compustat [260] and N–PORT data as of November 15, 2021 determine the size of U.S. entities referenced by total return, equity, and other non-CDS, debt security-based swaps, and jurisdiction of entities referenced by total return, equity, and other non-CDS, debt security-based swaps.[261] Using total assets and two digit ISIN country identifiers available from Compustat for the merged dataset, the analysis resulted in two distributions. The left distribution shows that 44% of entities referenced by TRS, equity security-based swaps, and other non-CDS, debt security-based swaps reported in Form N–PORT have total asset size less than $2 billion. The right figure shows that a significant majority, 59%, of entities referenced by TRS, equity security-based swaps, and other non-CDS, debt security-based swaps reported in Form N–PORT have underlying securities traded in the U.S.

Figure 9: The approximate distributions[a] of the size of firms referenced by total returns swap as reported in Form N-PORT (left) and the jurisdictions of the issues listing (right)



[a] Due to data limitations, no common indicators between the two data sets used in this analysis, COMPUSTAT and N-PORT, the Commission performed a name matching across the two data sets, which might lead to potential mismatch.

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This analysis indicates that there is likely a significant proportion of smaller to medium sized firms—including, for example, firms with less than $2 billion and between $2 and $6 billion in total book value of assets, respectively—which are underlying entities to total return, equity security-based swaps, and other non-CDS, debt security-based swaps as reported by funds that file Form N–PORT. In addition, the analysis indicates that the majority of these underlying entities have securities issued in the U.S. as identified by their two-digit ISIN code. A notional threshold (such as $300 million) would not capture the security-based swap exposure in the initial stages of accumulating a large position for a significant portion of smaller to medium sized firms. A $300 million notional exposure would correspond to a 5% percent threshold of an underlying entity with a $6 billion market capitalization. This would correspond to less than approximately 34% of underlying entities, entities with total assets greater than $6 billion. Hence, the requirement of a percent threshold would help inform the market of total return, equity security-based swaps, and other non-CDS, debt security-based swaps exposures for medium and smaller underlying entities.

While the Commission acknowledges that TRS, equity security-based swaps, and other non-CDS, debt security-based swaps exposures to the medium and smaller underlying entities do not pose large counterparty default risk compared to swap exposure on larger

[260] The analysis uses Compustat Global and Compustat North America. Compustat Global provides authoritative financial and market data covering publicly traded companies in more than 80 countries, representing over 90% of the world's market capitalization. Compustat Global includes coverage of over 96% of European market capitalization and 88% of Asian market capitalization.

[261] This analysis was subject to certain data limitations. In particular, the Compustat and N–PORT data contain no common identifiers between the two datasets. As a result, this might lead to potential mismatches because the merge was performed through a name-matching algorithm.

firms, security-based swaps based on securities issued by medium and smaller underlying entities have the potential to impact the underlying entity and its shareholders. This is likely because the underlying security referenced by such security-based swaps is more likely to be less liquid than underlying securities of large entities. The lower liquidity levels in the underlying security would be more prone to movement away from fundamentals because of offsetting activity in the total return, equity security-based swaps, and other non-CDS, debt security-based swaps. For example, Firm XYZ might buy TRS on underlying Firm ABC from Firm 123. To hedge its short exposure to the issued TRS, Firm 123 buys the underlying security of Firm ABC. Volatile market activity can result in margin calls from Firm 123 to Firm XYZ leading Firm 123 to sell some or all of its position in the underlying security. This quick and large selling of the underlying security by only one agent may trigger a more pronounced fire sale, which is a large sale of securities below market value. These sales dislocate the price away from its fundamental value.

A threshold based on the total number of shares attributable to the security-based swap position (as a percentage of the outstanding number of shares of that class of equity securities) could, however, help alleviate large changes in prices due to purchase or sales of the underlying security. Because this threshold would be tied to the outstanding number of shares, this threshold would effectively be lower for smaller firms—which would ensure that, when large positions are acquired, market participants could be made aware through Schedule 10B reports.

In addition, data analysis undertaken by the Commission staff shows that the number of investment companies that file Form N–PORT who would be captured by this new reporting requirement is likely to be small.[262] Other types of market participants that are not registered with the Commission under the Investment Company Act, such as family offices, endowments and private funds, may have lower risk aversion, higher TRS exposures, and may trigger the reporting threshold more than N–PORT filers.[263] The Commission estimates that 84% of the funds reporting on Form N–PORT as of November 15, 2021 hold an aggregate exposure of less than $300 million in TRS, while 14% of reporting funds have an aggregate exposure to TRS of $300 million or more. These percent estimates may not be indicative of the number of reports the Commission expect to receive.

E. Reasonable Alternatives

1. Implementing a More Prescriptive Approach in Re-Proposed Rule 9j–1

One potential alternative to the approach taken in re-proposed Rule 9j–1 would be to identify and prohibit within the rule specific types of events (for example, market behavior around certain events and fact patterns) and ''opportunistic trading'' behavior that have been observed. This alternative approach could provide even more certainty and precision with respect to the particular types of activities that are prohibited in the security-based swap market. This approach could, however, lead to greater uncertainty with respect to circumstances not explicitly contemplated in the rule, which could increase litigation costs for market participants involved in such transactions. This may also decrease the integrity of the market for security-based swaps, and in addition, could cause market participants to bear greater compliance costs in connection with the evaluation of circumstances not explicitly contemplated in the rule. As a result, the more prescriptive alternative approach would have limited benefits and greater costs as compared to the proposed approach in the market for security-based swaps, as well as the market for the referenced underlying of such security-based swaps.

2. Safe Harbor for Hedging Exposure Arising Out of Lending Activities

The Commission could add a conditional safe harbor from re-proposed Rule 9j–1 for entering into security-based swap transactions, while in possession of material non-public information, for purposes of hedging some or all exposure arising out of lending activities with a reference entity or the syndication of such lending activities. Such a conditional safe harbor could minimize the effects of the re-proposed rule on risk-reducing hedging activity, which is one of the central purposes of CDS contracts and which provides important benefits to the lending market. We believe that identifying legitimate, risk-reducing hedging activity—undertaken with the intent of covering potential losses in a position—and distinguishing such activity from other types of speculative transactions would likely be difficult. Hence, even a conditional safe harbor designed to apply solely to legitimate hedging transactions could unintentionally apply to activities proposed Rule 9j–1 is designed to prohibit, reducing the benefits of the rule. Further, such a conditional safe harbor would need to be balanced against the risk that market participants undertake transactions for which their counterparties should have the protections of the re-proposed Rule 9j–1, including in circumstances involving potentially opportunistic trading strategies.

3. Mandating That Security-Based Swap Data Repositories Report or Publicly Disclose Positions

The Commission could consider placing the reporting obligations on registered SBSDRs. Although this alternative would relieve market participants of additional reporting obligations and, given some reporting requirements are already in place, eliminate some additional reporting costs, this alternative would preclude inclusion in the reported data of key aspects of the reporting requirement proposed to be required by Rule 10B–1—the identity of the person building up a large security-based swap position and information regarding the underlying entity. Requiring that the SBSDRs report the applicable information would be subject to significant limitations that could undermine the effectiveness of the rule. Specifically, and as discussed above, Section 13(m)(1)(C)(iii) of the Exchange Act provides that any rulemaking pursuant to Section 13(m) (*i.e.,* Regulation SBSR) must be structured in such a manner ''that does not disclose the business transactions and market positions of any person.'' [264] Accordingly, such an alternative could involve only anonymized reporting, thereby negating one of the key benefits of the rule, *i.e.,* providing counterparties an opportunity to take certain protective actions when transacting with counterparties with a large, concentrated security-based swap position.

Further, this alternative would likely impose significant burdens on the SBSDRs, who would be required to report when the security-based swap entity breaches the specified gross

[262] *See* discussion related to the size of TRS holdings in Evaluation of Size and Jurisdiction of Underlying Entities Referenced by Total Return, Equity, and Other Non-CDS, Debt Security-Based Swaps.

[263] *See* discussion related to the limitation of Form N–PORT data in Evaluation of Size and Jurisdiction of Underlying Entities Referenced by Total Return, Equity, and Other Non-CDS, Debt Security-Based Swaps.

[264] *See* 15 U.S.C. 78m(m)(1)(C)(iii).

thresholds. This would likely require investments from the SBSDR in an automated reporting system, which would track, aggregate, monitor, and report exposures. In addition, given SBSDRs may not be aware of all positions held by a market participant, this alternative would limit the potential thresholds to only gross thresholds. These limitations could substantially undermine the benefits of the proposed rule.[265] This additional data provides important context for the information, such as whether holdings are hedged or not. In addition, if the rule were to require reporting of only gross thresholds, market participants may learn of large position buildup only. For example, a market participant may hold a large gross position that is net neutral (non-directional), just below the gross reporting threshold and not be required to report on Schedule 10B. Thereafter, the participant could quickly convert the gross position to a directional position by offloading the more liquid side of the trade, thus quickly converting the net neutral to a large directional position. As a result, the Commission does not believe this is the appropriate method of reporting.

4. Adopting Position Limits

Another possible alternative to proposed Rule 10B–1 and 9j–1 would be to adopt position limits in lieu of reporting requirements. These position limits would prohibit market participants from building up large, concentrated positions in security-based swaps. As compared with reporting, this would limit the ability of market participants to hedge underlying exposures. Further, given that transparency allows market participants to adjust counterparty exposures, it is unclear whether position limits would have substantially greater benefits to risk reduction and exposure to opportunistic strategies as compared with the proposed reporting. The Commission acknowledges, however, that to the extent that market participants would not make such adjustments, position limits could have risk reduction benefits beyond those associated with reporting.

5. Threshold Alternatives for Security-Based Swaps Based on Equity and Non-CDS Debt

The Commission could consider alternative approaches for calculating potential thresholds for security-based swaps based on equity and non-CDS debt. Specifically, the Commission could consider proposing reporting thresholds based on:

- The average daily trading volume (''ADTV'') of the relevant securities, such that reporting would be required if the number of shares represented by the security-based swap exceeded a certain percentage of ADTV.
- Notional values that vary based on types of equity underlying the equity-based swap, including for example, equity issued by emerging market issuers or large and small capitalization issuers. Such an alternative could resemble existing industry methodologies for calculating margin on derivatives.[266]
- For non-CDS debt, a bifurcated approach, such that the threshold would be defined to include both a threshold based on the notional amount of the position, and a threshold based on the percentage component (for example, notional divided by market value of total issuance).

Using a threshold that would adjust based on ADTV could better approximate when the market for an underlying security could be impacted with a large security-based swap, as compared to the proposed approach. For example, large positions relative to ADTV could affect the market for the underlying security if a party needed to exit that position in a short period of time, which could require having to liquidate any securities being held to hedge the security-based swap. Such a metric may not, however, be meaningful with respect to non-CDS debt security-based swaps, given that debt securities do not trade widely in the secondary market.

However, because these alternatives would be inconsistent with the proposed thresholds for CDS and be more complicated to calculate, they could increase compliance costs for market participants. Moreover, a metric based on ADTV would require security-based swap counterparties to monitor the trading volume of those shares, and because ADTV can fluctuate on a day-to-day basis, particularly during times of high volatility, such fluctuations could require persons trading large positions in security-based swaps to develop more sophisticated systems for monitoring those positions as a function of ADTV. A threshold that would vary based on the types of equity underlying the equity-based swap could potentially lead to additional computation complications. For example, it would require security-based swap market participants to track different thresholds for different types of underlying securities.

With respect to the potential inclusion of a bifurcated approach for non-CDS debt swaps, there would potentially not be a substantial benefit to including a percent component in this threshold. Specifically, comparing a notional amount to a bond market capitalization denominator would likely not indicate meaningful information about the holder's ability to affect the market for the underlying bond market. In addition, a calculation based on a bond market capitalization denominator[267] would be bond issue specific, making the calculation unique to every bond. This would likely increase the costs to market participants to maintain compliance.

6. Threshold Alternatives for Credit Default Swaps

An alternative approach to the public reporting requirement in Rule 10B–1 would be to consider different methodologies for calculating the reporting thresholds for single-name CDS. When considering different reporting methodologies for single-name CDS, the Commission also could consider proposing:

- A single gross threshold that would require single-name CDS trading entities to report their exposure and related holdings after the entity exceeds a certain level of their aggregate CDS exposure for a single underlying entity without accounting for offsetting deliverable securities. For example, even if a CDS market participant were net neutral (*i.e.,* no directional exposure), because it has large exposures both in the long and short direction it would have to reveal this information to the market at certain thresholds.
- A single net threshold that would require single-name CDS trading entities to report their exposure and related holdings after the entity exceeds a certain level of their net single-name CDS position (*i.e.,* allows the reporting entity to offset or account for hedged positions). This is one of the two components of the 10B–1 reporting threshold. This alternative would thus only capture large directional exposure.

[265] Even to the extent that anonymized data would be sufficient, the data provided to the SBSDRs pursuant to Regulation SBSR is unlikely to be useful as a way of potentially alleviating the compliance burdens of Rule 10B–1, absent a rulemaking to amend Regulation SBSR. For example, SBSDRs are currently permitted to apply a cap to the anonymized dissemination of CDS transactions, such that if the trade exceeds $5 million, it will be disseminated as ''$5MM+'' in lieu of the actual amount, mirroring how cash corporate bonds are disseminated by TRACE. In addition, data reported to an SBSDR relates only the security-based swaps themselves. By contrast, Section 10B–1 allows the Commission to require reporting of both a security-based swap position and any security or loan or group or narrow-based security index of securities or loans related to the security-based swap.

[266] *See, e.g.,* ''ISDA SIMM Methodology, version 2.3,'' *available at: https://www.isda.org/a/oDHTE/ISDA-SIMM-v2.3-PUBLIC.pdf.*

[267] In addition, this methodology would not capture private placement bonds as they are unregistered debt securities only sold to accredited investors.

• Thresholds based on net or gross notional of single-name CDS positions relative to total net or gross outstanding CDS, outstanding bonds, or total deliverable bonds related to the single-name CDS. For example, market participants could be required to report if their net CDS position, as discussed above, divided by total outstanding bonds exceeds, for example, a 5% threshold or other percent threshold.[268]

• Calculating the short notional amount threshold of $150 million by adding or subtracting the notional amount of any positions in a deliverable underlying debt security and/or calculating both the long and short $150 million notional amount thresholds by netting out any other Security Based Swap, specifically, single-name CDS with the same maturity, referencing the same underlying entity.

The first two alternative approaches may be a less burdensome means of achieving the goal of disclosing concentrated positions, as fewer reports would be required. We believe, however, that requiring only gross or netted reporting would substantially reduce the benefits of the proposed rule. Specifically, without a netted reporting requirement, market participants would not be aware of the true market exposure, while without a gross reporting requirement, a single-name CDS entity could present substantial systematic risks without triggering a reporting obligation. For example, if there is no requirement to report a net neutral position even though the aggregate gross position is significant, then the entity's position could quickly become directional by closing the offsetting position.[269] The same situation might happen for a small net exposure that is below the net reporting threshold, but with a large aggregate gross exposure.

Further, if the Commission were to use a single gross threshold, a selected threshold would have to be significantly lower than the one included in the proposal to capture market events similar to those captured under the proposed threshold. This would increase the overall number of reports and would likely capture a large number of positions immaterial to addressing asymmetric information problems. Each uninformative report would dilute the value of each informative report by increasing overall costs of processing and providing the required information to other market participants.

With respect to the third alternative, a threshold based on the notional of single-name CDS positions relative to total outstanding CDS, outstanding bonds, or total deliverable bonds would have the benefit of capturing more positions related to smaller underlying entities, which might be more prone to being impacted by opportunistic strategies compared to larger firms. This alternative could, however, be challenging for market participants to implement. First, it not clear how market participants would calculate total outstanding CDS, which could increase the costs of implementing the alternative. Second, unlike underlying securities for equity swaps, bonds with different vintages and yields are not fungible securities, meaning that they are not equivalent or interchangeable. As a result, selecting the ones to aggregate uniformly across all underlying entities when calculating the denominator increases the difficulty and costs of the calculation. For example, not all bonds would be deliverable into the auction for each of the CDS.

With respect to both (i) calculating the notional amount subject to the short notional amount threshold of $150 million by adding or subtracting the notional amount of any positions in a deliverable underlying debt security and (ii) calculating both the long and short $150 million notional amount thresholds by netting out the notional amount of any other Security Based Swap, specifically for single-name CDS where security-based swap would match the reference entity and the tenor, would reduce costs for market participants by potentially reducing the number of reports they would be required to file. However, these calculation methods would reduce the amount of information available to other market participants and, therefore, may not present the same counterparty risk reduction benefits.

7. Information Required To Be Reported on Schedule 10B

The Commission could propose that different information be reported on Schedule 10B. For example, the Commission could propose a version of Schedule 10B that would not require the public reporting of the identity of the filer. In this case, the market participant would inform the Commission about having exceeded the reporting threshold, but other market participants (counterparties, underlying reference entity, and other regulators) would not know or be able to identify the market participant that triggered the reporting obligation. This alternative would not allow market participants to know which counterparty they should change their behavior towards in order to reduce counterparty risk (for example, by adjusting prices to capture additional risk, increasing margin requirements, or decreasing trading activity). Market participants could treat all of their counterparties as if they exceeded the reporting threshold, potentially creating a chilling effect on the market. Accordingly, this alternative would not afford the same benefits of our proposed approach.

Alternatively, the Commission could propose that the rule require reporting the identity of the filer and not the underlying reference entity. Similarly, the Commission could propose the filer not to specify the size of the position, or information about the corresponding trading strategy. These alternatives would have the benefit of limiting the potential market reaction to the filer's trades and strategies, such as strategy replication or attempts to anticipate the filer's trading patterns. They would not, however, allow market participants to fully quantify nor understand the complete relationship the filer has with the underlying entity. This could cause an overreaction similar to the ones previously discussed, such as incentivizing counterparties to treat larger threshold breaches equally as smaller ones, or misinterpreting the strategy of the filer. Accordingly, the Commission does not believe that these alternatives would afford the same benefits of our proposed approach.

F. Request for Comment

The Commission requests comment on any aspect of the above economic analysis, including our description of the current economic baseline, the potential costs and benefits of the proposed amendments, their effect on efficiency, competition, and capital formation, and any reasonable alternatives we should consider. In addition, we request comment on the following aspects of the proposal:

• The Commission requests comment on the potential costs for security-based swap market participants, including costs attributable to the modification of market participants' business operations or supervisory practices or systems. The Commission also requests comments about any potential benefits resulting from the proposed Rule 9j–1, 10B–1, and 15Fh–4(c) for market participants and underlying entities. The

[268] For some underlying reference entities, it might be the case that there are significantly more CDS outstanding than bonds. Hence, the percent threshold could be greater than 100%.

[269] We provide an example of how a reporting entity might be able to ''hide'': The entity bought $300 million in CDS and simultaneously sold $300 million CDS, which yields a net exposure of zero and therefore no need to report under the net thresholds. When it becomes beneficial, the entity can relatively quickly obtain a directional net position of $300 million by selling either leg of the initial trade. This new position needs to be reported but the position is already in place and does not leave time for counterparties to adjust their positions in a timely manner.

Commission also seeks comments on the accuracy of any of the benefits identified and welcomes comments on any of the costs identified here. Finally, the Commission encourages commenters to identify, discuss, analyze, and supply relevant data, information, or statistics regarding any such costs or benefits. The Commission seeks specific comment and empirical data, if available, on the potential impact of the proposed rule.

- We solicit comment on any additional short-term and long-term benefits that could be realized with re-proposed Rule 9j–1, proposed Rule 10B–1, and proposed Rule 15Fh–4(c). Specifically, we solicit comment regarding benefits to the efficient operation of the security-based swap market, price efficiency, market integrity, and investor protection.
- We request comment on whether re-proposed Rule 9j–1, proposed Rule 10B–1, or proposed Rule 15Fh–4(c) would promote efficiency, competition, and capital formation or have an impact or burden on competition both in the security-based swap market and the underlying markets. Commenters are requested to provide empirical data and other factual support for their view to the extent possible.
- We solicit comment on costs associated with re-proposed Rule 9j–1, including whether the rule could discourage certain legitimate market activities, because of concern that such activities might be viewed as a violation of the rule. The Commission also requests specific comment on any changes to business operations or supervisory practices or systems that might be necessary to implement the proposed rule. In addition, the Commission solicits comment on any additional short-term and long-term costs that could result from proposed Rule 9j–1. Specifically, the Commission solicits comment regarding costs to the efficient operation of the security-based swap market, price efficiency, market integrity, and investor protection.
- The Commission solicits comment on the costs and benefits associated with the reporting thresholds for single-name CDS and TRS. Should these thresholds be lower or higher, and are there other alternative thresholds?
- The Commission solicits comment on the complexity of the reporting thresholds for single-name CDS, equity, and non-CDS security-based swaps. Should these thresholds be more complex, difficult to calculate, and precise, or simpler, easier to calculate, and broader, and are there other alternative thresholds?
- We solicit comment on costs associated with reporting of security-based swap positions as a result of proposed Rule 10B–1, including whether the rule would impose costs that could discourage market activity by creating indirectly position limits or liquidity pools.
- We solicit comment on any additional short-term and long-term benefits that could be realized with proposed Rule 10B–1. Specifically, the Commission solicits comment regarding benefits to the efficient operation of the security-based swap market, price efficiency, market integrity, and investor protection.
- The Commission solicits comment on benefits associated with reporting of security-based swap positions because of proposed Rule 10B–1, including whether the rule would give rise to additional benefits that could encourage capital formation for underlying entities. The Commission solicits comment on any long-term or short-term costs that might influence underlying entities because of reporting thresholds. How might underlying entities change funding practices or procedures under proposed Rule 10B–1?

VII. Consideration of Impact on the Economy

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, (''SBREFA''),[270] the Commission requests comment on the potential effect of the proposed rules on the economy on an annual basis. The Commission also requests comment on any potential increases in costs or prices for consumers or individual industries, and any potential effect on competition, investment, or innovation. Commenters are requested to provide empirical data and other factual support for their views to the extent possible.

VIII. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (''RFA'')[271] requires Federal agencies, in promulgating rules, to consider the impact of those rules on small entities. Section 603(a) of the Administrative Procedure Act,[272] as amended by the RFA, generally requires the Commission to undertake a regulatory flexibility analysis of all proposed rules, or proposed rule amendments, to determine the impact of such rulemaking on ''small entities.''[273] Section 605(b) of the RFA states that this requirement shall not apply to any proposed rule or proposed rule amendment which, if adopted, would not have a significant economic impact on a substantial number of small entities.[274]

For purposes of Commission rulemaking in connection with the RFA, a small entity includes: (1) When used with reference to an ''issuer'' or a ''person,'' other than an investment company, an ''issuer'' or ''person'' that, on the last day of its most recent fiscal year, had total assets of $5 million or less;[275] or (2) a broker-dealer with total capital (net worth plus subordinated liabilities) of less than $500,000 on the date in the prior fiscal year as of which its audited financial statements were prepared pursuant to 17 CFR 240.17a–5(d) (''Rule 17a–5(d)'') under the Exchange Act,[276] or, if not required to file such statements, a broker-dealer with total capital (net worth plus subordinated liabilities) of less than $500,000 on the last business day of the preceding fiscal year (or in the time that it has been in business, if shorter); and is not affiliated with any person (other than a natural person) that is not a small business or small organization.[277]

Based on available information about the security-based swap market, the market, while broad in scope, is largely dominated by entities such as those that will be covered by the SBSD and MSBSP definitions. Based on feedback from industry participants about the security-based swap market, the Commission continues to believe that: (1) The types of entities that are and will continue to register with the Commission as SBSDs (*i.e.,* because they engage in more than a de minimis amount of dealing activity involving security-based swaps)—which generally would be large financial institutions—would not be ''small entities'' for purposes of the RFA; and (2) the types of entities that may have security-based swap positions above the level required to register as MSBSPs would not be

[270] Public Law 104–121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C., 15 U.S.C., and as a note to 5 U.S.C. 601).

[271] 5 U.S.C. 601 *et seq.*

[272] 5 U.S.C. 603(a).

[273] Although Section 601(b) of the RFA defines the term ''small entity,'' the statute permits agencies to formulate their own definitions. The Commission has adopted definitions for the term ''small entity'' for the purposes of Commission rulemaking in accordance with the RFA. Those definitions, as relevant to this proposed rulemaking, are set forth in 17 CFR 240.0–10 (''Rule 0–10'') under the Exchange Act. *See* Exchange Act Release No. 18452 (Jan. 28, 1982), 47 FR 5215 (Feb. 4, 1982) (File No. AS–305).

[274] *See* 5 U.S.C. 605(b).

[275] *See* 17 CFR 240.0–10(a).

[276] 17 CFR 240.17a–5(d).

[277] *See* 17 CFR 240.0–10(c).

''small entities'' for purposes of the RFA.

Although proposed Rule 15Fh–4(c) would apply only to SBS Entities, re-proposed Rule 9j–1 and proposed Rule 10B–1 (including proposed Schedule 10B) are not on their face limited to SBS Entities. However, while it is possible that other parties may engage in security-based swap transactions, the Commission does not believe that any such entities would be ''small entities'' as defined in Exchange Act Rule 0–10.[278] Feedback from industry participants about the security-based swap market indicates that only persons or entities with assets significantly in excess of $5 million (or with annual receipts significantly in excess of $7 million) participate in the security-based swap market. With respect to re-proposed Rule 9j–1, even to the extent that a small number transactions did have a counterparty that was defined as a ''small entity'' under the Rule 0–10, the Commission believes it unlikely that the re-proposed rule would have a significant economic impact on such entities, as the rule prohibits fraudulent and manipulative acts, activities which are in most cases already prohibited. Finally, the Commission believes that the proposed reporting thresholds in proposed Rule 10B–1 are set sufficiently high as to further mitigate against the possibility of proposed Rule 10B–1 (including Schedule 10B) applying to persons who would be considered ''small entities'' under Rule 0–10.

For the foregoing reasons, the Commission certifies that proposed Rules 9j–1, 10B–1 (including Schedule 10B), and 15Fh–4(c), if adopted, would not have a significant economic impact on a substantial number of small entities for purposes of the RFA. The Commission invites commenters to address whether the proposed rules would have a significant economic impact on a substantial number of small entities, and, if so, what would be the nature of any impact on small entities. The Commission requests that commenters provide empirical data to illustrate the extent of the impact.

IX. Statutory Authority

The Commission is proposing the new rules and rule amendment contained in this release under the authority set forth in the Exchange Act, 15 U.S.C. 78a *et seq.,* as amended, and, particularly Sections 2, 3(b), 9(i), 9(j), 10, 10B, 15, 15F, and 23(a) thereof (15 U.S.C. 78b, 78c(b), 78i(i), 78i(j), 78j, 78j–2, 78o, 78o–10, and 78w(a)).

[278] *See* 17 CFR 240.0–10(a).

List of Subjects in 17 CFR Part 240

Administrative practice and procedure, Brokers, Confidential business information, Fraud, Reporting and recordkeeping requirements, Securities, Swaps.

Text of the Proposed Rule

For the reasons set forth in the preamble, title 17, chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The general authority citation for part 240 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78j–2, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78o, 78o–4, 78o–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78dd, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.,* and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; Pub. L. 111–203, 939A, 124 Stat. 1376 (2010); and Pub. L. 112–106, sec. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

■ 2. Add § 240.9j–1 to read as follows:

§ 240.9j–1 Prohibition against fraud, manipulation, or deception in connection with security-based swaps.

(a) It shall be unlawful for any person, directly or indirectly, to purchase or sell, or attempt to induce the purchase or sale of, any security-based swap; to effect any transaction in, or attempt to effect any transaction in, any security-based swap; to take any action to exercise any right, or any action related to performance of any obligation, under any security-based swap, including in connection with any payments, deliveries, rights, or obligations or alterations of any rights thereunder; or to terminate (other than on its scheduled maturity date) or settle any security-based swap, in connection with which such person:

(1) Employs or attempts to employ any device, scheme, or artifice to defraud or manipulate; or

(2) Makes or attempts to make any untrue statement of a material fact, or omits to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or

(3) Obtains or attempts to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(4) Engages or attempts to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person;

(b) It shall be unlawful for any person to, directly or indirectly, manipulate or attempt to manipulate the price or valuation of any security-based swap, or any payment or delivery related thereto.

(c) Wherever communicating, or purchasing or selling a security (other than a security-based swap) while in possession of, material nonpublic information would violate, or result in liability to any purchaser or seller of the security under either the Act or the Securities Act of 1933, or any rule or regulation thereunder, such conduct in connection with a purchase or sale of a security-based swap with respect to such security or with respect to a group or index of securities including such security shall also violate, and result in comparable liability to any purchaser or seller of that security under, such provision, rule, or regulation.

(d) Whenever taking any of the actions set forth in paragraphs (a) or (b) of this section involving a security-based swap would violate, or result in liability under Section 9(j) of the Act or this section, such conduct, when taken by a counterparty to such security-based swap (or any affiliate of, or a person acting in concert with, such security-based swap counterparty in furtherance of such prohibited activity), in connection with a purchase or sale of a security or group or index of securities on which such security-based swap is based, shall also violate, and shall be deemed a violation of, Section 9(j) of the Act or paragraphs (a) or (b) of this section.

(e) For purposes of this section, the terms ''purchase'' and ''sale'' shall have the same meanings as set forth in Sections 3(a)(13) (15 U.S.C. 78c(a)(13)) and 3(a)(14) (15 U.S.C. 78c(a)(14)) of the Act.

(f) A person shall not be liable under paragraph (a) of this section solely for reason of being aware of material non-public information while taking the following actions:

(1) Actions taken by a person in accordance with binding contractual rights and obligations under a security-based swap (as reflected in the written security-based swap documentation governing such transaction or any amendment thereto) so long as:

(i) The security-based swap was entered into, or the amendment was made, before the person came into

possession of such material non-public information; and

(ii) The entry into, and the terms of, the security-based swap are themselves not a violation of any provision of this section.

(2) Security-based swap transactions effected by a person pursuant to a bilateral portfolio compression exercise (as defined in § 240.15Fi–1(a)) or a multilateral portfolio compression exercise (as defined in § 240.15Fi–1(j)) so long as:

(i) Any such transactions are consistent with all of the terms of a bilateral portfolio compression exercise or multilateral portfolio compression exercise, including as it relates to, without limitation, the transactions to be included in the exercise, the risk tolerances of the persons participating in the exercise, and the methodology used in the exercise; and

(ii) All such terms were agreed to by all participants of the bilateral portfolio compression exercise or multilateral portfolio compression exercise prior to the commencement of the applicable exercise.

■ 3. Add an undesignated center heading and § 240.10B–1 to read as follows:

Requirements and Reports Under Section 10B

§ 240.10B–1 Reporting of Security-based Swap Positions.

(a) *Reporting obligation.*

(1) Any person (and any entity controlling, controlled by or under common control with such person), or group of persons, who through any contract, arrangement, understanding or relationship, after acquiring or selling directly or indirectly, any security-based swap, is directly or indirectly the owner or seller of a security-based swap position that exceeds the reporting threshold amount, shall file with the Commission a statement containing the information required by § 240.10B–101 (Schedule 10B) on the Commission's Electronic Data Gathering, Analysis and Retrieval System (EDGAR).

(2) Any Schedule 10B required by this section shall be filed promptly, but in no event later than the end of the first business day following the day of execution of the security-based swap transaction that results in the security-based swap position first exceeding the reporting threshold amount.

(3) A group's filing obligation pursuant to paragraph (a)(1) of this section may be satisfied either by a single joint filing or by each of the group's members making an individual filing. If the group's members elect to make their own filings, each such filing should identify all members of the group but the information provided concerning the other persons making the filing need only reflect information which the filing person knows or has reason to know.

(4) Any person who, directly or indirectly, creates or uses a trust, proxy, power of attorney, pooling arrangement or any other contract, arrangement, or device as part of a plan or scheme to evade the reporting requirements of paragraph (a)(1) of this section with respect to a security-based swap position shall be deemed for purposes of this section to be the owner of such security-based swap position.

(b) *Definitions.* For purposes of this section:

(1) The term *reporting threshold amount* shall mean:

(i) With respect to credit default swaps (including credit default swaps where the underlying reference is a group or index of entities or obligations of entities that is a narrow-based security index), the lesser of:

(A) A long notional amount of $150 million, calculated by subtracting the notional amount of any long positions in a deliverable debt security underlying a security-based swap included in the security-based swap position from the long notional amount of the security-based swap position;

(B) A short notional amount of $150 million; or

(C) A gross notional amount of $300 million.

(ii) With respect to security-based swap positions based on debt securities that are not credit default swaps, a gross notional amount of $300 million.

(iii) With respect to security-based swap positions based on equity securities, the lesser of:

(A) A gross notional amount of $300 million; *provided, however,* that if the gross notional amount of the security-based swap position exceeds $150 million, the calculation of the security-based swap position shall also include the value of all of the underlying equity securities owned by the holder of the security-based swap position (based on the most recent closing price of shares), as well as the delta-adjusted notional amount of any options, security futures, or any other derivative instruments based on the same class of equity securities; or

(B) A security-based swap equivalent position that represents more than 5% of a class of equity securities; *provided, however,* that if the security-based swap equivalent position represents more than 2.5% of a class of equity securities, the calculation of the security-based swap equivalent position shall also include in the numerator all of the underlying equity securities owned by the holder of the security-based swap position, as well as the number of shares attributable to any options, security futures, or any other derivative instruments based on the same class of equity securities.

(2) The term *security-based swap equivalent position* shall mean the number of shares attributable to all of the security-based swaps comprising a security-based swap position, as determined in accordance with paragraph (b)(4) of this section.

(3) The term s*ecurity-based swap position* shall mean all security-based swaps based on:

(i) A single security or loan, or a narrow-based security index, or any interest therein or based on the value thereof;

(ii) Any securities issued by the same issuer (each, an ''issuing entity'') the securities, loans, or securities included in the narrow-based index (including any interest therein or based on the value thereof) described in paragraph (b)(3)(i); or

(iii) Any narrow-based security index that includes any of those issuing entities or their securities (including any interest therein or based on the value thereof), in each case as applicable. To the extent that a security-based swap position is based on a single security or loan that is included in a narrow-based security index, the calculation of the security-based swap position with respect to a particular component of the index would be based on the weighting of the reference entity or securities as a component of the index. With respect to security-based swaps based on equity securities, a security-based swap position shall include all security-based swaps based on a single class of equity securities.

(4) When used in paragraphs (b)(1)(iii)(B) and (b)(2) of this section, the ''number of shares attributable'' to a derivative instrument (including a security-based swap) shall mean the *larger* of (in each case as applicable):

(i) The number of shares of the reference equity security that may be delivered upon on the exercise of the rights under the derivative instrument, as determined in accordance with the terms of the applicable documentation;

(ii) The number of shares of the reference equity security determined by multiplying the number of shares by reference to which the amount payable under the derivative instrument is determined by the delta of the applicable derivative instrument; and

(iii) The number of shares of the reference equity determined by:

(A) Dividing the notional amount of such derivative instrument by the most recent closing price of shares of the reference equity security; and then

(B) Multiplying such quotient by the delta of the applicable derivative instrument.

(5) For purposes of paragraph (b)(1)(i) of this section, a ''debt security underlying a security-based swap included in the security-based swap position'' means any security that could potentially be deliverable into a credit default swap auction in the event of a default.

(6) For purposes of paragraphs (b)(1)(iii)(A) and (b)(4) of this section, the term ''delta'' shall mean the ratio that that is obtained by comparing (x) the change in the value of a derivative instrument to (y) the change in the value of the reference equity security. If a derivative instrument does not have a fixed delta, then the delta should be calculated on a daily basis, based on the most recent closing price of shares of the reference equity security.

(7) For purposes of paragraph (b)(1)(iii)(A) and (B) of this section, a person that is a member of a national securities exchange shall not be deemed to be the owner of any equity securities that they hold directly or indirectly on behalf of another person solely because such person is the record holder of such securities and, pursuant to the rules of such exchange, may direct the vote of such securities, without instruction, on other than contested matters or matters that may affect substantially the rights or privileges of the holders of the securities to be voted, but is otherwise precluded by the rules of such exchange from voting without instruction.

(c) *Amendments.* If any material change occurs in the facts set forth in a previously filed Schedule 10B including, but not limited to, any material increase in the security-based swap positions or if a security-based swap position falls back below the applicable reporting threshold amount, the person or persons who were required to file the statement shall file or cause to be filed with the Commission an amendment disclosing that change. All such amendments shall be filed on EDGAR promptly, but in no event later than the end of the first business day following the material change. For purposes of this paragraph (c), a change equal to 10% or more of a position previously disclosed in Schedule 10B shall be deemed ''material'' for purposes of this section.

(d) *Applicability.* The requirements of this section shall apply to all security-based swap positions so long as:

(1) Any of the transactions that comprise the security-based swap position would be required to be reported pursuant to § 242.908(a) of this chapter (Rule 908 of Regulation SBSR); or

(2) The reporting person holds any amount of reference securities underlying the security-based swap position (or would be deemed to be the beneficial owner of such reference securities, pursuant to Section 13(d) of the Act (15 U.S.C. 78m) and the rules and regulations thereunder), *and:*

(i) The issuer of such reference security is a partnership, corporation, trust, investment vehicle, or other legal person organized, incorporated, or established under the laws of the U.S. or having its principal place of business in the U.S.; or

(ii) Such reference security is part a class of securities registered under Section 12 or 15(d) of the Exchange Act.

(e) If some or all of the information required to be disclosed on Schedule 10B is publicly available on EDGAR at the time the Schedule 10B is required to be filed, such information may be incorporated by reference in answer, or partial answer, to any item of Schedule 10B.

■ 4. Add § 240.10B–101 to read as follows:

§ 240.10B–101 Schedule 10B—Information to be included in statements filed pursuant to § 240.10B–1(a) and amendments thereto filed pursuant to § 240.10B–1(c).

Securities and Exchange Commission, Washington, DC 20549 Schedule 10B Under the Securities Exchange Act of 1934 (Amendment No. __) * (Name, Address, Email Address and Telephone Number of Person Authorized To Receive Notices and Communications) (Date of Event Which Requires Filing of This Statement or Any Amendment Thereto As Required by Rule 10B–1(c))

(1) State the name of the reporting person (or names of reporting persons if making a joint filing as a group). State if the reporting person is a member of a group. If the reporting person is a member of a group and the members of the group are satisfying the group's Rule 10B–1(a)(1) (§ 240.10B–1(a)(1)) filing obligation by making individual filings, identify all members of the group.

(2) State the residency or place of organization of the reporting person(s).

(3) State the type of reporting person(s) (see instructions).

(4) For reporting persons that are legal entities, state the Legal Entity Identifier (LEI) of the reporting person(s), if such person(s) has an LEI.

(5) State the notional amount of the applicable security-based swap position(s), as defined in Rule 10B–1(b)(3) (§ 240.10B–1(b)(3)), of the reporting person(s), along with summary information about the composition of the position as it relates to the direction (*i.e.,* long or short) and the tenor/expiration of the underlying security-based swap transactions and the product ID (17 CFR 242.900(bb)) of the security-based swap(s) included in the security-based swap position, if applicable.

(6) In the case of a security-based swap position based on debt securities (including credit default swaps), state the ownership of: (i) All debt securities underlying a security-based swap included in the security-based swap position, including the Financial Instrument Global Identifier (FIGI) of each underlying debt security, if applicable, and the LEI of the issuer of each underlying debt security, if the issuer has an LEI; and (ii) all security-based swaps based on equity securities issued by the same reference entity, including the FIGI of each underlying equity security, if applicable. In addition to the FIGI, other unique security identifier(s) may be included at the filer's option.

(7) In the case of a security-based swap position based on equity securities, state the ownership of: (i) All equity securities underlying a security-based swap included in the security-based swap position, including the FIGI of each underlying equity security, if applicable, and the LEI of the issuer of each underlying equity security, if the issuer has an LEI; and (ii) all security-based swaps based on debt securities issued by the same reference entity (including credit default swaps), including the FIGI of each underlying debt security, if applicable. In addition to the FIGI, other unique security identifier(s) may be included at the filer's option.

(8) State the ownership of any other instrument relating to the security-based swap position and/or any underlying security or loan or group or index of securities or loans, or any security or group or index of securities, the price, yield, value, or volatility of which, or of which any interest therein, is the basis for a material term of a security-based swap included in the security-based swap position, if not otherwise disclosed pursuant to Items 6 or 7 of this statement. For any underlying security disclosed pursuant to this Item, disclose the FIGI of the security, if applicable, and the LEI of the issuer of the security, if the issuer has an LEI. In addition to the FIGI, other unique security identifier(s) may be included at the filer's option.

(9) To the extent that the reporting threshold amount, as defined in Rule 10B–1(b)(1) (§ 240.10B–1(b)(1)), is based on the number of shares corresponding to a security-based swap position based on equity securities, state the number of shares attributable to the security-based swap position, along with the closing price used in the calculation and the date of such closing price.

Instructions to Schedule 10B

(1) *Type of Reporting Person*—Please classify each ''reporting person'' according to the following breakdown and place the appropriate symbol (or symbols, *i.e.,* if more than one is

applicable, insert all applicable symbols) on the form:

Category	Symbol
Broker Dealer	BD
Security-Based Swap Dealer or Major Security-Based Swap Participant	SBSE
Bank	BK
Insurance Company	IC
Investment Company	IV
Investment Adviser	IA
Employee Benefit Plan or Endowment Fund	EP
Parent Holding Company/Control Person	HC
Savings Association	SA
Church Plan	CP
Corporation	CO
Partnership	PN
Individual	IN
Other	OO

(2) *Incorporation by Reference*—Rule 10B–1(e) (§ 240.10B–1(e)) provides that if some or all of the information required to be disclosed on Schedule 10B is publicly available on EDGAR at the time the Schedule 10B is required to be filed, such information may be incorporated by reference in answer, or partial answer, to any item of Schedule 10B. Include an express statement clearly describing the specific location of the information you are incorporating by reference. You must include an active hyperlink to information incorporated into Schedule 10B to the applicable link to EDGAR). The information must not be incorporated by reference in any case where such incorporation would render the disclosure incomplete, unclear, or confusing. For example, disclosure must not be incorporated by reference from a second document if that second document incorporates information pertinent to such disclosure by reference to a third document.

Signature. After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

Date

Signature

Name/Title

The original statement shall be signed by each person on whose behalf the statement is filed or their authorized representative. If the statement is signed on behalf of a person by their authorized representative (other than an executive officer or general partner of the reporting person), evidence of the representative's authority to sign on behalf of such person shall be filed with the statement, provided however, that a power of attorney for this purpose which is already on file with the Commission may be incorporated by reference.

Attention—Intentional misstatements or omissions of fact constitute Federal criminal violations (See 18 U.S.C. 1001).

■ 5. Amend § 240.15Fh–4 by adding paragraph (c) to read as follows:

§ 240.15Fh–4 Antifraud provisions for security-based swap dealers and major security-based swap participants; special requirements for security-based swap dealers acting as advisors to special entities.

* * * * *

(c) *No undue influence over chief compliance officer.* It shall be unlawful for any officer, director, supervised person, or employee of a security-based swap dealer or major security-based swap participant, or any person acting under such person's direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the security-based swap dealer's or major security-based swap participant's chief compliance officer in the performance of their duties under the Federal securities laws or the rules and regulations thereunder.

By the Commission.

Dated: December 15, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–27531 Filed 2–3–22; 8:45 am]

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 10, 12, 16, *et al.*
National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 12, 16, and 205

[Docket No. FDA–2020–N–1663]

RIN 0910–AH11

National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing national standards for the licensing of prescription drug wholesale distributors (''wholesale distributors'' or ''wholesale drug distributors'') and third-party logistics providers (''3PLs''), as directed under the Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality and Security Act). Pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the DSCSA, the proposed rule would establish standards for all State and Federal licenses issued.

DATES: Submit either electronic or written comments on the proposed rule by June 6, 2022. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 7, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on June 6, 2022. Electronic comments must be submitted on or before that date. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions in the following ways:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1663 for ''National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is ''National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers.''

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4261, Silver Spring, MD 20993, 301–796–3130. With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Proposed Rule

The Drug Quality and Security Act (DQSA) was enacted on November 27, 2013. Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA), includes provisions designed to strengthen the integrity of the pharmaceutical distribution supply chain. Among other measures, section 204 of the DSCSA amends section 503(e) of the FD&C Act (21 U.S.C. 353(e)), which requires licensure of prescription drug wholesale distributors (wholesale distributors or wholesale drug distributors or WDDs) and adds section 583 to the FD&C Act (21 U.S.C. 360eee–2), which requires FDA to establish by regulation national standards for the licensure of prescription drug wholesale distributors. Section 205 of the DSCSA adds section 584 to the FD&C Act (21 U.S.C. 360eee–3), which requires licensure of third-party logistics providers and requires FDA to establish, by regulation, national standards for the licensure of third-party logistics providers.

This proposed regulation, when finalized, will establish the national standards for the licensure of wholesale drug distributors and 3PLs required under sections 583 and 584 of the FD&C Act, as amended by the DSCSA. As required by statute, the standards, terms and conditions for licensure established by this regulation will apply to both Federal and State licenses (503(e)(1)(B), 583(b), and 584(a)(1)(A) of the FD&C Act).

As discussed in section X (Federalism), section 585(b)(1) of the FD&C Act (21 U.S.C. 360eee–4(b)(1)) preempts States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the national standards and requirements applicable under sections 584 and 503(e) of the FD&C Act. However, the statutory provisions themselves do not establish these ''standards and requirements''; instead, this regulation, once effective, will establish them. Accordingly, State and local licensure requirements will be preempted only once this regulation, when finalized, takes effect; until such time, current licensing of WDDs and 3PLs may continue. As discussed below, this determination will help avoid supply chain disruption, based on licensing uncertainties, during the period between DSCSA's enactment and the effective date of this regulation. Avoiding such interim period supply chain issues accords with Congress's overall intent to secure and strengthen the supply chain, as evidenced by other FD&C Act provisions added by DSCSA that recognize State licensure of WDDs and 3PLs prior to this regulation becoming effective.

In addition, pursuant to section 585(c) of the FD&C Act (21 U.S.C. 360eee–4(c)), regulation of areas within the historical police powers of the States would be unaffected by this regulation, including prohibiting employees of WDDs and 3PLs from engaging in criminal activity related to prescription drugs, provided that the State requirements involved are not related to licensure of 3PLs or WDDs.

The requirements for state licensing of wholesale distributors are currently established under 21 CFR part 205, and FDA is now proposing the withdrawal of that regulation and for part 205 to be replaced with this proposed rule. Where a state from which a drug is being distributed has not established a licensing program in accordance with the regulation, the DSCSA establishes FDA as the licensing authority for wholesale distributor and 3PL licenses (sections 503(e)(1)(A)(i)(II) and 584(a)(1)(B) of the FD&C Act). When finalized, the national standards set forth in the proposed rule will provide greater assurance that these supply chain participants are sufficiently vetted and qualified to distribute products, further strengthening the supply chain and the safety of prescription drugs provided to American consumers.

When finalized, this proposed rule will also set forth the standards applicable to, and the requirements for approval of, third-party organizations involved in the licensure and inspection process (''approved organizations'' or ''AOs''). Sections 583(c) and 584(d)(2)(A) of the FD&C Act provide, respectively, that FDA may approve ''third-party accreditation'' or inspection services or programs to conduct inspections of facilities used by wholesale distributors seeking licensure and to review the qualifications of 3PLs for licensure. This proposed rule will also address the standards and requirements for approving such third-party accreditation or inspection services or programs.

Overall, this proposed rule is designed to ensure that the supply chain remains secure and that those prescription drugs subject to the DSCSA that are moving through the supply chain are properly stored, handled, and transported. These measures are intended to help protect American consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.

For purposes of this proposed rule, FDA has defined ''entity'' or ''entities'' to mean a business organization, such as a corporation, company, association, firm, partnership, society, or joint stock company. Unless otherwise noted, the term ''3PL'' or ''third-party logistics provider'' in this proposed rule includes both the 3PL entity and the individual 3PL facilities requiring a license.

B. Summary of the Major Provisions of the Proposed Rule

FDA is proposing to replace the current part 205 with a new part 205 that will implement the licensure requirements of the DSCSA and govern licensure of 3PLs and wholesale distributors. When finalized, the new part 205 will replace the existing part 205 in its entirety. Subpart A will set forth the national licensing standards for State and Federal licenses issued to 3PLs pursuant to section 584 of the FD&C Act, and subpart C will set forth the national licensing standards for State and Federal licenses issued to wholesale distributors pursuant to sections 503(e) (as amended) and 583 of the FD&C Act. Subparts B and D will set forth the applicable standards and processes for approved organizations to perform licensure reviews and conduct inspections.

1. National Standards for the Licensure of Third-Party Logistics Providers

The DSCSA identifies 3PLs as separate members of the drug supply chain—distinct from wholesale drug distributors—and specifically precludes States from regulating 3PLs as wholesale distributors (585(b)(2) of the FD&C Act). FDA is required by section 584 of the FD&C Act to establish national standards for the licensure of 3PLs, and

the Agency is proposing those standards in subpart A of proposed part 205. When finalized, each facility of an entity meeting the definition of a 3PL in section 581(22) of the FD&C Act (21 U.S.C. 360eee(22)) will be required to be licensed by a State or Federal licensing authority in accordance with the standards articulated in subpart A of proposed part 205.

2. National Standards for the Licensure of Wholesale Drug Distributors

Prior to DSCSA's enactment, wholesale distributors engaging in interstate commerce were required to be licensed by the State in which they were operating pursuant to section 503(e)(2) of the FD&C Act (as then in effect). This section established minimum standards, terms, and conditions for licensing of wholesale distributors pre-DSCSA. As required by sections 503(e)(1)(B) (as amended by the DSCSA) and 583 of the FD&C Act, FDA is proposing to establish national standards, terms, and conditions through this rulemaking for the licensure of wholesale distributors that, when final, will apply to all State licensing programs as well as to the new Federal licensing program to be operated by FDA. These new standards would replace the previous standards set forth in current part 205.

3. Approval of Third Parties To Conduct Licensure Reviews and Inspections

In accordance with section 584(d)(2)(A) of the FD&C Act, FDA is proposing to establish a process by which third-party organizations will be approved by FDA to review a 3PL's qualifications for licensure. In addition, in accordance with section 583(c) of the FD&C Act, FDA is proposing to establish a process by which third-party organizations will be approved by FDA to conduct inspections of wholesale distributors for the purpose of licensure.

4. Conforming Changes

The regulation also proposes to amend 21 CFR 10.50(c) and 12.21(a)(2), which list statutory authorities that provide the opportunity for a formal evidentiary public hearing under 21 CFR part 12. Because the regulation proposes that wholesale distributors and 3PLs could request a formal evidentiary public hearing under part 12 for review of decisions affecting the denial, suspension, or revocation of 3PL or wholesale distributor licenses issued by the Secretary of Health and Human Services (Secretary), sections 503(e), 583, and 584 of the FD&C Act would be added to the list of statutory sections under which there is the opportunity for a hearing under §§ 10.50(c) and 12.21(a)(2), regarding such decisions. We are also proposing a conforming change to 21 CFR 16.1(b) to describe procedures for regulatory hearings that would add actions related to approved organizations under proposed §§ 205.19 and 205.33 respectively, including revocation or suspension of approval, to the list of actions for which a regulatory hearing under 21 CFR part 16 may be held.

C. Legal Authority

We are issuing this proposed rule under sections 301, 501, 502, 503(e), 582, 583, 584, 585, 701(a), and 704 of the FD&C Act (21 U.S.C. 331, 351, 352, 353(e), 360eee–1, 360eee–2, 360eee–3, 360eee–4, 371(a), and 374).

D. Costs and Benefits

In this rulemaking, we propose new national standards for the licensing of prescription drug wholesale distributors and third-party logistics providers as directed under the Drug Supply Chain Security Act, Title II of the Drug Quality and Security Act. If finalized, the rule would also establish a Federal licensing system for wholesale drug distributors and third-party logistics providers to use in the absence of a state licensure program that is consistent with the proposed national standards.

The standards for prescription drug wholesale distribution in the proposed rule would result in benefits to consumers and benefits to distributors from reducing the diversion of prescription drugs. Other monetized benefits include cost savings from reducing the frequency and quantity of licensure applications and cost savings from reducing state licensing standards in some states. We estimate that the annualized benefits over 10 years would range from $1.25 million to $31.50 million at a 7 percent discount rate, with a primary estimate of $10.66 million. We estimate that the annualized benefits would range from $1.26 million to $32.18 million at a 3 percent discount rate, with a primary estimate of $10.89 million.

We also expect that the proposed rule, if finalized, would impose costs on wholesale drug distributors, third-party logistics providers, states, approved organizations, and the Food and Drug Administration (FDA). Costs to wholesale drug distributors and third-party logistics providers include costs of learning about the rule, reporting to FDA, undergoing routine inspections, writing and revising standard operating procedures, and conducting background checks. Wholesale-drug distributors would also incur costs to furnish surety bonds to their state licensing authority to obtain or renew their licenses.

Costs to states include the time spent reading and understanding the rule, passing or revising the laws and regulations governing their licensure programs, and inspecting WDD and 3PL facilities. Approved organizations would incur legal, application, and training costs, as well as costs to inspect WDD and 3PL facilities. FDA costs include the costs to establish and operate a reporting database and a licensure program for wholesale drug distributors and third-party logistics providers and the costs to establish and operate an approval program for approved organizations.

We estimate that the annualized costs over 10 years would range from $13.21 million to $20.63 million at a 7 percent discount rate, with a primary estimate of $16.92 million. We estimate that the annualized costs over 10 years at a 3 percent discount rate would range from $12.83 million to $20.10 million, with a primary estimate of $16.47 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/ acronym	What it means
3PL	Third-Party Logistics Provider.
AO	Approved Organization.
CFR	Code of Federal Regulations.
DSCSA	Drug Supply Chain Security Act.
DQSA	Drug Quality and Security Act.
FDA or the Agency.	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.

III. Background

A. Introduction

The DSCSA (Title II of Pub. L. 113–54) was signed into law on November 27, 2013, to better protect the U.S. drug supply chain. FDA's implementation of the DSCSA includes many activities, including this proposed rule. Once final, this rule will establish national standards for licensure of wholesale distributors and 3PLs, as required by the DSCSA. For information on additional FDA activities related to the DSCSA, a web page describing FDA's implementation activities can be found at: *https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm.*

B. Need for the Regulation: The DSCSA and Establishment of National Standards for Licensure

The U.S. drug supply chain remains one of the safest in the world. However, the increasingly globalized nature of the supply chain brings with it complexities

that increase threats to the safety and security of the U.S. drug supply. A breach at any point in the supply chain carries potential for dangerous, and even deadly, outcomes for American consumers.

In passing the DSCSA, Congress recognized the need for national standards for the storage, handling, and transport of prescription drugs and directed FDA, in sections 583(a) and 584(d) of the FD&C Act, to establish such standards by regulation for WDDs and 3PLs, respectively. These national standards will help diminish opportunities for dangerous and criminal conduct affecting the supply of prescription drugs in the United States. When final, every U.S. wholesale distributor and 3PL facility will be held to these standards through the statute's licensure requirements. Where a State does not have a licensing program in accordance with the regulation, FDA will be the licensing authority.

This proposed rule, when finalized, will provide much needed certainty and clarity for wholesale distributors and 3PLs seeking licensure. In passing the DSCSA, Congress believed the existing system of different regulation regarding supply chain security by each state created a patchwork system of governance and that a uniform national standard would address this concern. See statements of Senator Mikulski (Ref 1), Congressmen Mathis (Ref 2) and Congressman Latta (Ref 3).

Requirements for wholesale distributors currently vary significantly across State lines, and many wholesale distributors and 3PLs have facilities in multiple States. Specifically, State requirements and standards for licensure can vary on topics such as the length of time for which records must be maintained; qualifications of facility managers and designated representatives; facility requirements; licensure duration; renewal procedures; exemptions from the definition of wholesale distribution; and inspection and approval requirements by certain, specific organizations in order to receive licensure in certain States. This proposed rule, when finalized will be an important first step in harmonizing these requirements, thus allowing for greater compliance and management of licensure.

Additionally, we note that commenters on FDA's draft guidance entitled ''The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers'' (Ref 4) agreed that creation of a uniform national standard for licensure, through the issuance of these regulations, should be the goal of FDA (see, *e.g.,* Ref 5). Commenters noted that the patchwork of licensing standards was precisely the regulatory burden that the DSCSA was intended to eliminate. (see, *e.g.,* Ref 6) Comments added that tracking and complying with different standards in different States on a continuing basis would be very time consuming and add unnecessary costs to the distribution chain (see, *e.g.,* Ref 7).

We believe that the issuance of these regulations, when finalized, will provide far greater clarity to both States and regulated industry as to the requirements and expectations FDA has with respect to licensure. The publication of these regulations, when finalized, and the approach to preemption discussed in this document will reflect the national standard Congress intended, but will detail FDA's expectations with respect to licensure. This will allow for greater certainty in the logistics and distribution industry, and in the supply chain as a whole.

Since the passage of DSCSA, States have implemented disparate policies with respect to licensure of 3PLs. Some States repealed or eliminated 3PL as a licensure category, others are waiting for FDA to publish its regulations before determining how to proceed, some are licensing 3PLs under some other form of licensure, and some do not regulate 3PLs at all (Ref 8). These regulations, when finalized, will provide certainty and clarity in the logistics industry.

The Agency believes finalizing these proposed regulations is crucial to implementation of licensure of 3PLs as intended by DSCSA. Under section 582(a)(7) of the FD&C Act (21 U.S.C. 360eee–1(a)(7)), 3PLs are deemed licensed until the effective date of these regulations unless the Secretary has made a finding that the 3PL does not utilize good handling and distribution practices and publishes notice thereof. Until these regulations are issued, and the framework for licensure established, the Agency cannot institute the provisions and the goals of DSCSA—to further secure the supply chain by including 3PLs as an authorized member of the supply chain through the licensure provisions, which will ensure that they are appropriately credentialed, inspected, and therefore duly qualified to participate in the supply chain.

Theft and diversion of prescription drugs continue to be major issues, contributing to drug shortages and creating significant financial losses, the effects of which cascade throughout the supply chain to consumers. FDA has observed that these instances often involve products distributed by unlicensed wholesale distributors. FDA standards, oversight, and regulations, including to implement the requirements of DSCSA, will lessen and hopefully eliminate product diversion in the legitimate supply chain. According to the National Association of Boards of Pharmacy (NABP)'s 2013 report entitled ''Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply,'' drug diverters and bad actors seek out gaps in the distribution and regulatory structure, specifically seeking out States whose licensure framework is less stringent (Ref. 9). This proposed rule, when finalized, and the preemption of inconsistent State provisions will remedy this forum shopping for drug diverters who seek to take advantage of the lack of uniform framework.

Additionally, NABP's 2013 report also contends that the so-called ''five percent rule'' is a policy that has been ripe for exploitation due to the policy being inconsistently legislated, interpreted, and enforced from State to State. This was a policy under which FDA had previously concluded that sales of prescription drugs by a retail pharmacy to licensed practitioners for office use would be considered to be minimal and not constitute wholesale distribution, if the total dollar volume of these sales does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales (see further discussion in ''Definitions'' section below). However, this interpretation was not codified. The NABP observed that ''pharmacies acting as wholesalers have been found to take advantage of the parameters set by some States [regarding minimal quantities] when it comes to drug distribution. Rather than dispensing the drugs as mandated, these pharmacies retain them to resell to wholesalers at an amount exceeding the specified quantity of prescription medications as permitted in certain States (often times 5% of annual sales). Some have gone as far as to sell their entire inventory into the gray market'' This proposed rule, when finalized, codifies the principle that the five percent rule only applies to pharmacy sales for office use. Sales above five percent for office use, or any sales to a wholesale distributor, require the pharmacy to become licensed and regulated as a wholesale distributor. This proposed rule will clarify this requirement and close a potential loophole that could lead to diversion of products and excessive sales from dispensers who are not licensed and registered as wholesale distributors

when they are engaging in wholesale distribution.

Unlicensed wholesale distribution has been a major source of diverted products both leaving and reentering the supply chain. Significant amounts of drug diversion involve wholesale distributors, either diverting the product themselves from the supply chain, or purchasing product that was diverted by another actor. The DSCSA, which requires uniform national standards for licensure of wholesale distributors, will cut down on these types of instances of diversion since supply chain trading partners are required to transact with only other trading partners who meet the strict requirements laid out in these regulations. There are many examples of diversion and criminal action by wholesale distributors under the current regulatory scheme, which these regulations, when finalized, will discourage, or possibly even prevent, in the future.

As an example, from 2007–2014, individuals involved with the Minnesota Independent Cooperative bought prescription drugs from a network of illegal and unlicensed sources and sold approximately $393 million worth of diverted prescription drugs to wholesalers and retail pharmacies throughout the United States. These individuals falsified transactional documents, as well as licensure documents, to enter into fraudulent transactions with dispensers and other wholesalers. In a 2008 example detailed in the indictment, the unlicensed individuals involved allegedly bought a truckload of stolen asthma inhalers for $662,000 and sold them through the Minnesota Independent Collective to another wholesaler for about $1 million (Ref 10). These regulations, when finalized, and the DSCSA requirements that trading partners only transact with authorized, licensed trading partners, and verify suspect and illegitimate product, will make these schemes far more difficult to achieve. Had DSCSA been the prevailing regulatory scheme at the time, other wholesale distributors and dispensers would have been deterred from doing business with the Minnesota Independent Collective because they were not an authorized trading partner.

In 2014, two individuals pleaded guilty to their involvement in a drug diversion and distribution scheme through an entity called Cumberland Distribution. Both defendants admitted that Cumberland Distribution purchased prescription drugs from individuals and entities that were not licensed to engage in the wholesale distribution of prescription drugs and were not authorized to distribute prescription drugs. Cumberland Distribution then distributed these products to dispensers. The prescription drugs were acquired through various networks of ''diverters'' who obtained prescription drugs from other unlawful sources. As a result, Cumberland Distribution could not lawfully resell the drugs. Pharmacies throughout the United States purchased these diverted prescription drugs from Cumberland Distribution under the guise that the products had been in the custody of licensed wholesale distributors or other authorized distributors since being sold by the original manufacturer (Ref 11). Under DSCSA, the licensure status of these purported wholesale distributors is easily searchable and verifiable, thus making diversion schemes, such as this, far more difficult to achieve. In addition to requiring FDA to establish national licensure standards, the DSCSA outlines critical steps for building an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States (section 582(g) of the FD&C Act). This system will enhance FDA's ability to protect American consumers from exposure to drugs that may be unfit for distribution and will increase efficiency in the detection and removal of potentially dangerous drugs from the U.S. drug supply chain.

The FD&C Act, as amended by DSCSA, requires FDA to establish national standards for the licensure of two critical members of the supply chain: wholesale drug distributors and 3PLs. It also requires that only those wholesale distributors and 3PL facilities licensed according to these national standards may engage in wholesale distribution or 3PL activities, respectively. Only licensed wholesale drug distributors and 3PLs whose facilities are so licensed will be considered ''authorized trading partners'' permitted under the FD&C Act, as amended by DSCSA, to engage in transactions related to the sale and distribution of certain prescription drugs with other members of the supply chain.

To create the standards proposed in the regulations, FDA conducted a comprehensive review of existing State standards for licensure including storing, handling, and holding prescription drugs, as well as other nationally recognized standards and model rules for wholesale distribution and logistics, such as those created by the NABP (Ref 12), Healthcare Distribution Alliance (Ref 13), World Health Organization (Ref 14), and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) (Ref 15). The Agency believes that the proposed standards align with existing practices and will help ensure that 3PL and wholesale distribution activities are undertaken in a manner that minimizes diversion and threats to the regulated supply chain.

C. Changes From the Prescription Drug Marketing Act (PDMA)

Prior to the DSCSA's enactment, the last comprehensive legislative action related to prescription drug distribution was the Prescription Drug Marketing Act of 1987 (PDMA) (Pub. L. 100–293). Among other things, the PDMA required wholesale distributors to obtain licenses from States in which they were operating (sec. 6 of the PDMA; also see FDA's 2001 Report to Congress on the PDMA (Ref 16)). Under the PDMA, FDA promulgated regulations that established minimum standards, terms, and conditions for licensure of wholesale distributors. The PDMA provided neither a specific definition of 3PL-type entities nor specific oversight over them; without a distinct regulatory framework for 3PLs, some States chose to regulate and license 3PLs as wholesale distributors, with some others choosing to license 3PLs as separate entities. The DSCSA requires that all wholesale distributor and 3PL licenses meet the standards established by FDA (sections 503(e)(1)(B) and 584(a) of the FD&C Act), and that 3PLs not be licensed as wholesale distributors (section 585(b)(2) of the FD&C Act).

If an entity owns a facility in which it is engaging in 3PL activities and wholesale distribution out of the same facility, the entity will be required to hold a 3PL license and a separate wholesale distributor license for the distinct functions they perform.

IV. Legal Authority

The Agency is proposing this rule under the authority to propose national standards for the licensing of wholesale distributors and 3PLs granted to it by various sections of the FD&C Act, including sections 301, 503(e), 582, 583, 584, 585, 701(a), and 704 (21 U.S.C. 331, 351, 352, 353(e), 360eee–1, 360eee–2, 360eee–3, 360eee–4, 371(a), and 374).

Section 503(e) requires wholesale distributors to be licensed according to the standards, terms, and conditions established by the Secretary, and section 583 requires FDA to establish by regulation national standards for the licensure of prescription drug wholesale distributors. Section 584 requires 3PLs to be licensed according to standards established in regulations promulgated

by FDA for the licensure of 3PLs. Section 301(t) prohibits the failure to comply with the requirements under sections 584 and 503(e). Section 301 also prohibits a number of actions concerning adulterated and misbranded drugs. Section 585 provides that states cannot implement licensing standards, requirements, or regulations that are inconsistent with, less stringent than, directly related to, or covered by the standards applicable under sections 503(e) and 584. Section 585 also precludes states from regulating 3PLs as wholesale distributors. To enforce these and other provisions of the FD&C Act, section 704 authorizes FDA to conduct inspections. Section 701(a) of the FD&C Act provides general authority to issue regulations for the efficient enforcement of the FD&C Act. By establishing national standards for the licensing of wholesale distributors and 3PLs, this rule, when finalized, is expected to aid in the efficient administration and enforcement of the FD&C Act, and in particular would help efficiently enforce the provisions relating to licensure of wholesale drug distributors and 3PLs.

V. Description of the Proposed Rule

The national standards for the licensure of 3PLs, required by section 584 of the FD&C Act, as amended by DSCSA, are set forth in subpart A of proposed part 205. The national standards for the licensure of wholesale distributors, required by sections 503(e) and 583 of the FD&C Act, as amended by DSCSA, are set forth in subpart C of proposed part 205. The process and standards for third-party accreditation programs to become approved by the Federal Government to evaluate the qualifications of 3PLs for licensure, as required by section 584(d) of the FD&C Act, are established in subpart B of proposed part 205. The process and standards for third-party accreditation and inspection services to become approved by the Federal Government to conduct inspections of wholesale distributors, as permitted by section 583(c) of the FD&C Act, are set forth in subpart D of proposed part 205.

A. Scope/Applicability (Proposed §§ 205.1 and 205.2)

In accordance with section 584 of the FD&C Act, FDA is proposing to establish the national standards for licensing by State and Federal licensing authorities set forth in subpart A of part 205 that would apply to 3PL facilities in any State (see proposed § 205.1). Furthermore, in accordance with section 503(e)(1) of the FD&C Act, FDA is proposing to establish the national standards for wholesale distributors set forth in subpart C of part 205 that would apply to wholesale distributors of prescription drugs in any State (see proposed § 205.1). The standards, terms, and conditions for licensure established under part 205, subparts A and C, once finalized, would apply to all State and Federal 3PL and wholesale distributor licenses.

All 3PL facilities are required to obtain a 3PL license for each facility of such 3PL. The FD&C Act, as amended by DSCSA, prohibits States from regulating 3PLs as wholesale distributors. A 3PL that also engages in wholesale distribution in the same facility in which it engages in 3PL activities must obtain a separate wholesale distribution license (see proposed § 205.1).

An entity is considered a wholesale distributor if the entity is engaged in the distribution of a drug subject to section 503(b) (relating to prescription drugs) of the FD&C Act (21 U.S.C. 353(b)), to a person other than a consumer or patient, with a few exclusions. Under section 201(g) of the FD&C Act (21 U.S.C. 321(g)), a drug includes a bulk drug substance, and under current FDA regulations, the term *bulk drug substance* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances (21 CFR 203.3(e)). FDA believes that the distribution of bulk drug substances must have the same safeguards and provisions as the distribution of finished drug products. The same safeguards that prevent diversion and theft and secure the pharmaceutical distribution supply chain generally must include the transfer of bulk drug substances, as they are subject to the same concerns as the distribution of prescription drugs in finished dosage form.

FDA is proposing to establish the process and standards that would apply to any third-party accreditation or inspection services seeking to obtain or maintain approval by FDA to evaluate qualifications of 3PLs for licensure or to conduct inspections of wholesale distributors (see proposed § 205.1). Once finalized, proposed subparts B and D of part 205 would establish the process and standards for third-party accreditation and inspection services to become approved by the Secretary to review the qualifications of 3PLs for licensure, as required by section 584(d) of the FD&C Act, and to conduct inspections of wholesale distributors, as permitted by section 583(c) of the FD&C Act (see proposed § 205.2) (*i.e.,* to become ''approved organizations'').

B. Definitions (Proposed § 205.3)

By its terms, the definitions of terms in section 581 of the FD&C Act (21 U.S.C. 360eee) applies in subchapter H. However, because those terms are also used throughout section 503(e) of the FD&C Act (as amended by the DSCSA), FDA considers the definitions and interpretations contained in section 581 of the FD&C Act to apply to those terms when used in proposed part 205. Specifically, the definitions of the following terms contained in section 581 of the FD&C Act apply when used in proposed part 205: Affiliate, authorized, dispenser, illegitimate product, licensed, manufacturer, product, repackager, return, specific patient need, suspect product, third-party logistics provider, and wholesale distributor. In addition, FDA is proposing the definition of the following additional terms to help clarify the requirements. FDA believes that these proposed definitions align with existing law and regulations, as well as current industry practices.

- *3PL Activities:* Includes warehousing and ''other logistics services'' that are undertaken with respect to a product (as defined in proposed § 205.3(k)).
- *Change of Entity Ownership:* Recognizing that businesses often undergo changes in corporate structure through mergers, acquisitions, and other transactions, FDA proposes that ''change of entity ownership'' be defined to help ensure consistency with regard to how such changes will affect licensure. The definition describes the events that would constitute a change in ownership with respect to a partnership, unincorporated sole proprietorship, corporation, or limited liability company.
- *Co-Licensed Partner:* One of two or more entities that have entered into an agreement for the right to engage in the marketing of a prescription drug. The Agency believes this definition is in alignment with industry practice and existing laws.
- *Designated Representative:* An individual who is designated as the representative of the facility manager and, as such, is identified by the licensee as responsible for managing the daily operation of the establishment in compliance with licensure requirements and has the authority to implement corrective action when necessary. This individual is also responsible for ensuring that personnel are appropriately qualified, assigned, and

trained to accomplish their duties. The Agency believes this definition reflects current practices and understanding.

- *Entity or Entities:* A business organization, such as a corporation, company, association, firm, partnership, society, sole proprietorship, or joint stock company.
- *Facility:* A site at one general, permanent, physical location used to store or handle prescription drugs. For purposes of proposed part 205, a facility does not include a site, such as a corporate office or headquarters, where the sole activity conducted at the site is one of oversight, support, or business administrative function.
- *Key Personnel:* Any individual who has responsibility for managing the operations of the wholesale distributor, including any principal, owner, director, officer of the wholesale distributor, designated representatives, and other individuals who are authorized to enter areas where prescription drugs are held and are likely to handle those prescription drugs as a part their responsibilities within the operation.

○ Section 583(b)(5) of the FD&C Act, as amended by DSCSA, requires that FDA establish standards for the ''establishment and implementation of qualifications for key personnel'' of wholesale distributors. These key personnel must be sufficiently qualified and screened to carry out the important responsibilities that come with positions within a wholesale distribution company. FDA believes individuals who hold these positions must be held to a high standard of qualification as they are entrusted with important aspects of protecting the pharmaceutical distribution supply chain.

- *Minimal Quantities:* An annual dollar volume of prescription drugs sold by a retail pharmacy to licensed practitioners for office use that does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales.

○ Section 503(e)(4) of the FD&C Act excludes a number of activities from the definition of wholesale distribution. One excluded category, listed at section 503(e)(4)(E) of the FD&C Act, is ''the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use.'' FDA has previously considered what constitutes minimal quantities in determining when the practices of a retail pharmacy become wholesale drug distribution and thereby subject to licensure (see 64 FR 67720, December 3, 1999). For example, in preamble discussions around codifying provisions related to wholesale distribution, FDA proposed a minimal quantities limit, considered comments, and ultimately concluded that sales of prescription drugs by a retail pharmacy to licensed practitioners for office use would be considered to be minimal and not wholesale distribution, if the total dollar volume of these sales does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales.

○ The Agency continues to maintain its position that a 5-percent limit to what constitutes minimal quantities is sufficient ''to meet the needs of licensed practitioners who may not purchase enough prescription drugs to go through a wholesale distributor and thus may not otherwise be able to easily obtain drugs for office use'' (64 FR 67720 at 67748). We believe this standard is still relevant and is the industry standard. We note that in January 2013, the NABP passed a resolution that supports limiting the five percent rule to allow for transfer ''between pharmacies, or from pharmacy to or from pharmacies to practitioners, only for the purpose of dispensing or administration, but not for resale; and to prohibit the transfer, distribution, or sale of prescription drugs from pharmacies to wholesalers for resale'' (Ref 17). The transfer or sale from dispenser to dispenser for a specific patient need is already considered to not be wholesale distribution under the FD&C Act (see section 503(e)(4)). This NABP resolution accords with FDA's proposed definition of *minimal quantities.* We request comment on the codification of this 5 percent limit for office use and of the definition of *minimal quantities.*

○ Accordingly, a licensed retail pharmacy that distributes more than 5 percent of its annual sales to licensed practitioners is engaging in wholesale distribution, subject to all the requirements for wholesale distributors, unless its activities are otherwise excluded from the definition of wholesale distribution. The exemption for distributing minimal quantities of drugs by retail pharmacies to licensed practitioners for office use was ''not created to confer a special benefit on retail pharmacies, but to meet the legitimate need of licensed practitioners'' (64 FR 67720 at 67748). For purposes of section 503(e)(4)(E) of the FD&C Act, FDA is proposing to codify its position on ''minimal quantities'' in the proposed § 205.3(h) to mean the ''total annual dollar amount sold to licensed practitioners for office use does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription drug sales.''

○ The Agency also notes that this exclusion only applies to sales of prescription drugs from licensed pharmacies to licensed practitioners for office use. FDA understands that some States and other entities have expanded the applicability of this exclusion from the definition of wholesale distribution to allow for distribution from pharmacies to other entities outside of licensed practitioners for office use, but FDA notes that this practice is not allowed under current Federal law. The statutory language at section 503(e)(4)(E) of the FD&C Act specifically limits the exclusion to the distribution of minimal quantities of a drug between a licensed retail pharmacy and a licensed practitioner for office use. Unless a specific sale or transfer of a drug from one dispenser to another dispenser is outside of the definition of wholesale distribution because it is to a consumer or patient (*e.g.,* to fulfill a ''specific patient need,'' as defined at section 581(19) of the FD&C Act), a pharmacy that sells or trades prescription drugs to other pharmacies or other entities falls within the definition of wholesale distribution. Such activity is considered wholesale distribution under section 503(e)(4) of the FD&C Act, subject to all the requirements of wholesale distributors.

- *Other Logistics Services:* Services provided by entities that accept or transfer direct possession of products from that entity's facility within the United States and its territories on behalf of a trading partner (*e.g.,* manufacturer, wholesale distributor, dispenser), but that do not take ownership of the product or have the responsibility to direct a product's sale or disposition. It also includes services undertaken with respect to a product for a repackager that is acting on behalf of a manufacturer, wholesale distributor, or dispenser.

○ Under the DSCSA, the definition of 3PL includes entities that conduct ''other logistics services'' on behalf of a manufacturer, wholesale distributor, or dispenser of a product. The Agency recognizes that 3PLs may perform 3PL activities for repackagers and proposes to include in the definition of ''other logistics services'' those services undertaken with respect to a product for a repackager acting on behalf of a manufacturer, wholesale distributor, or dispenser.

○ Under this proposed definition, a common carrier that only transports a product, but does not take ownership of the product, is not conducting ''other logistic services.'' Similarly, an entity

that directs the sale or disposition of the product but does not take possession (such as a broker) would not be conducting ''other logistics services'' and does not meet the definition of a 3PL, but may be engaged in activities that meet the definition of a manufacturer or wholesale distributor.

• *Other Than a Consumer or Patient:* A person receiving the drug who is not (i) the individual identified as the recipient of the prescription drug, (ii) a dispenser fulfilling a specific patient need, or (iii) the clinical investigator, as defined in 21 CFR 312.3(b) (or any successor regulation).

○ FDA considers certain types of prescription drug distribution as outside the scope of ''wholesale distribution'' under section 503(e)(4) of the FD&C Act because they constitute ''the distribution of a drug'' to a ''consumer or patient,'' which is excluded from the definition of wholesale distribution. The first of these is the distribution to, or receipt by, the patient, who, for purposes of DSCSA, FDA considers to be the individual intended to take or be administered the prescription drug. This would typically be the individual whose name appears on the prescription.

○ FDA also considers the transfer or sale of a drug from one dispenser to another to fulfill a ''specific patient need'' to be outside the scope of wholesale distribution. Specific patient need is defined at section 581(19) of the FD&C Act as ''the transfer of a product from one pharmacy to another to fill a prescription for an identified patient.'' FDA would note, however, that a dispenser who transfers or sells a drug to a trading partner other than another dispenser, or to another dispenser where there is no specific patient need evidenced by a prescription, is distributing a drug to someone other than a consumer or patient, which, if not otherwise excluded under section 503(e)(4) of the FD&C Act, would be engaging in wholesale drug distribution requiring a wholesale distributor license.

○ Finally, FDA considers the sale or transfer of a drug for investigational or research purposes to an investigator, as defined in 21 CFR 312.3 (or any successor regulation), under an investigational new drug application (IND) submitted to FDA to be outside the scope of wholesale distribution because the drug is used for in vitro, clinical, or other research purposes under an IND.

○ For these reasons, FDA is proposing to exclude these types of transactions from the scope of wholesale distribution.

• *Product:* A prescription drug in a finished dosage form that is ready for administration to a patient without substantial further manufacturing (*e.g.,* capsules, tablets, lyophilized products before reconstitution).

○ The definition of ''product'' proposed here is broader and more inclusive than that used for purposes of product tracing detailed in section 582 of the FD&C Act as defined in section 581(13). As used in section 584 of the FD&C Act for purposes of licensure of a 3PL, the term ''product'' excludes active pharmaceutical ingredients intended for incorporation into a finished drug product but have yet to undergo substantial further manufacturing to become the finished dosage form for administration. Of note, for purposes of section 582 of the FD&C Act (21 U.S.C. 360eee–1), the definition for ''product'' excludes certain types of prescription drugs in finished dosage form (section 581(13) of the FD&C Act).

• *Significant Disciplinary Action:* Any action by a State or Federal licensing authority that would limit or prevent a 3PL from conducting 3PL activities, or would limit or prevent a wholesale distributor from distributing or facilitating the distribution of prescription drugs. This includes suspension or revocation of a 3PL or wholesale distributor license, State controlled substances license, or Drug Enforcement Administration (DEA) registration, and potentially includes other disciplinary actions such as a consent decree or final ruling of a State licensure board, depending on the impact on the 3PL's or wholesale distributor's legal ability to perform licensed activities.

• *Unfit for Distribution:* A prescription drug that has been identified as a drug whose sale would violate the FD&C Act. This definition includes prescription drugs identified as suspect or illegitimate (582(c)(4) of the FD&C Act); adulterated, including drugs rendered nonsaleable because conditions (such as return, recall, damage, or expiry) cast doubt on the drug's safety, identity, strength, quality, or purity (section 501 of the FD&C Act); or misbranded (section 502 of the FD&C Act (21 U.S.C. 352)).

○ FDA believes that prescription drugs unfit for distribution must be segregated from those that are fit for distribution to protect patients from receiving potentially defective or harmful prescription drugs and prevent the distribution of drugs that are unfit for distribution.

○ A wholesale distributor or 3PL could potentially identify a prescription drug as unfit for distribution through their own examination of incoming and outgoing shipments of prescription drugs as outlined by proposed 21 CFR 205.12(c)(1) for 3PLs and 205.26(c)(4) for wholesale distributors, through inventory review under proposed 21 CFR 205.12(c)(4)(i) for 3PLs and 205.26(c)(5)(i)(B) for wholesale distributors, through other internal means designed to detect product that is unfit for distribution, or be notified of a prescription drug's status as unfit for distribution by a trading partner or others.

• *Wholesale distribution:*

○ Section 503(e)(4) of the FD&C Act defines wholesale distribution as ''the distribution of a drug subject to [section 503(b) of the FD&C Act] to a person other than a consumer or patient, or receipt of a drug subject to [section 503(b) of the FD&C Act] by a person other than the consumer or patient.'' The definition then goes on to list 19 activities that are not considered wholesale distribution. Of these, FDA is providing clarification about several that may be causing some confusion for industry and the States.

○ Section 503(e)(4)(C) of the FD&C Act states that the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, does not constitute wholesale distribution. In addition to distribution of a drug during a declared public health emergency pursuant to section 319 of the Public Health Service Act, FDA considers the following circumstances to constitute emergency medical reasons and therefore be excluded from the definition of wholesale distribution: (1) The distribution of a drug to a first responder or other authorized individual administering prescription drugs to acutely ill or injured persons in an emergency situation and outside a healthcare facility, and (2) a long-term care facility receiving an emergency kit containing drugs for use in emergency situations to treat acutely ill or injured persons during hours of the day when necessary drugs cannot be obtained from a dispenser. Pursuant to 503(e)(4)(C) of the FD&C Act, this exclusion from the definition of wholesale distribution does not include distributing a drug during a shortage unless such shortage was caused by a public health emergency.

○ The exclusion at section 503(e)(4)(E) of the FD&C Act for the distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for

office use is discussed in the description of the term ''minimal quantities.''

○ Section 503(e)(4)(H) of the FD&C Act excludes ''the distribution of a drug by the manufacturer of such drug'' from wholesale distribution. Therefore, FDA considers the activities of a manufacturer, as defined at section 581(10) of the FD&C Act, when distributing its own drug, as excluded from the definition of wholesale distribution and not subject to the requirements that apply to wholesale distributors. FDA believes this is supported by the term ''wholesale distributor,'' which is defined at section 581(29) of the FD&C Act, in relevant part, as ''a person (other than a manufacturer, a manufacturer's co-licensed partner . . .) engaged in wholesale distribution.'' The Agency notes, however, that if Manufacturer A purchases and distributes Manufacturer B's drug, for which Manufacturer A has no affiliation and is not a co-licensed partner, Manufacturer A is engaged in wholesale distribution, subject to all the requirements for wholesale distributors.

C. National Standards for Third-Party Logistics Providers

1. 3PL Licensure

3PL facilities are required to be licensed in order to conduct activities in any State (section 584 of the FD&C Act). As such, the proposed regulation provides that a 3PL facility may not conduct 3PL activities unless it is licensed by the State from which it conducts 3PL activities, or by FDA if the State from which 3PL activities are conducted has not established a licensure program in accordance with the regulations, as set forth in section 584(a) of the FD&C Act (see proposed § 205.4(a)). In addition, the requirement in 584(a) of the FD&C Act that each facility of the 3PL must be licensed, such that a 3PL with multiple facilities in a single State will have multiple licenses from that State, is set forth in proposed § 205.4(b).

Under FDA's proposed regulation, if a 3PL owns or leases a facility serving as a warehouse for products, the State in which the facility is located will be considered the State from which the 3PL ''conducts activities'' and will be the State from which the 3PL must obtain a license for that facility under proposed § 205.4(a)(1). FDA understands there has been some confusion about whether an entity hired or contracted by another trading partner to provide labor, logistic, or administrative services for that trading partner in that trading partner's facility would be considered a 3PL. This could occur, for example, where a wholesale distributor hires a contractor to provide such support services from within the wholesale distributor's facility exclusively for that wholesale distributor. In this scenario, the contractor's activities from within the wholesale distributor's licensed facility would be captured by the wholesale distributor's license and obligations for compliance, and the facility would not be considered a 3PL or required to have a 3PL license. However, an entity that operates a facility in which it engages in wholesale distribution and performs 3PL activities on behalf of other trading partners for products it does not own or direct the sale or disposition of is required to obtain both a wholesale distributor and 3PL license for that facility.

Additionally, pursuant to section 584(a)(2) of the FD&C Act, if a product is distributed in interstate commerce, the 3PL must be licensed by the State into which the product is distributed if that State requires such license; however, section 584(a)(2) of the FD&C Act also provides that if the 3PL is licensed by FDA, as described in section 584(a)(1)(B), the 3PL is not required to obtain a license from the State into which the product is distributed (see proposed § 205.4(a)(3)). Finally, to ensure that a facility and those responsible for its operations meet the licensing standards, FDA proposes to require that 3PL licenses be facility- and owner-specific and not transferable to another establishment or owner (see proposed § 205.4(c)). 3PL licenses must be held at the licensed facility and must be made available to State, Federal, or other licensing authorities upon request (see proposed § 205.4(d)).

Section 584 states that the national licensing standards for 3PLs established by regulation take effect 1 year after the date such final regulation is published (section 584(d)(1) and (3) of the FD&C Act). National licensing standards for wholesale distributors established by regulation take effect 2 years after the date such final regulation is published (section 583(a) and (e)(3) of the FD&C Act). For several reasons, including those discussed below, FDA does not intend to enforce the licensing requirements for 3PLs until 2 years after the final regulation is published.

FDA recognizes that 1 year may be insufficient time for States to implement 3PL licensure programs, should they decide to implement such a program, and for 3PLs to apply for licensure under these programs. Setting up a state licensure program may require additional time. This is especially true in States that will require State legislative action to implement a licensure program, with some State legislatures only meeting biennially.

Considering these factors, FDA does not intend to enforce these requirements with respect to the national standards for licensure until 2 years after the regulation is finalized. This will help ensure there is time for States to establish or modify their licensure programs in accordance with the new standards and time for 3PLs to apply and obtain a new license.

For 1 year after the effective date of the final regulation, FDA also does not intend to enforce the requirements of section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act with respect to a manufacturer, wholesale distributor, dispenser, or repackager who has as a trading partner a 3PL that is not licensed, unless the 3PL is not licensed because the Secretary or a state licensing body has made a finding that the 3PL does not utilize good handling and distribution practices and has published notice thereof.

2. General Application Requirements for Licensure

The general requirements that must be met for a State or Federal licensing authority to issue a license to a 3PL facility are proposed in § 205.5. As proposed, § 205.5(a) includes requirements applicable to the individual who submits the application and states that the applicant must submit all required information and pay any applicable licensing fee to be issued a license.

The information that would be required as part of a 3PL's application for licensure of a facility is set forth in proposed § 205.5(b). FDA believes this information is necessary for the licensing authority to assess whether the 3PL is in good standing and has the infrastructure and capabilities to fulfill its duties and obligations under these national standards for 3PL licensure. This includes disclosing whether the 3PL facility manager or designated representative has ever been convicted of a felony relating to prescription drug distribution (see proposed § 205.5(b)(7)). FDA believes that this information is crucial to protect the integrity of the prescription drug supply chain by ensuring that those responsible for the daily operations of a 3PL facility do not have a history of violating the FD&C Act. In addition, in its application for licensure renewal, under proposed § 205.7, a 3PL would be required to certify that the 3PL facility has continually met the requirements of § 205.5 and will inform the licensing authority of certain changes to

information if such changes have not already been submitted to the licensing authority (see proposed § 205.5(c)).

3. The Federal Licensure Process

Section 584(a)(1)(B) of the FD&C Act gives FDA the authority to license 3PLs directly if the State from which a 3PL conducts 3PL activities has not established a licensure requirement in accordance with the regulations. The process that FDA will use for issuing licenses to 3PLs is detailed in proposed § 205.6. While § 205.6 is only applicable to 3PLs obtaining a license from FDA, FDA suggests that States implement similar procedures. FDA intends to help stakeholders understand who the appropriate licensing authority is in the 3PL's State.

The FDA licensure process begins when a 3PL seeking licensure for a facility submits an application to FDA for review and consideration (see proposed § 205.6(a)). The DSCSA permits FDA to approve third-party organizations, referred to as approved organizations or AOs, to evaluate a 3PL's qualifications for licensure (section 584(d)(2)(A)–(B) and 584(e) of the FD&C Act). If FDA has approved one or more organizations to review a 3PL's qualifications for licensure, a 3PL should note the AO it prefers on its application. FDA generally intends to review a 3PL's qualifications for licensure only if the review cannot be completed by an FDA-approved AO. The licensure review consists of a review of all documents submitted in support of the application and an inspection of the facility pursuant to proposed § 205.16. FDA intends for the licensure application process to be electronic (see proposed § 205.6(a)) and to leverage existing technologies to streamline the licensure process.

While the DSCSA permits AOs to review a 3PL's qualifications for licensure and to recommend to FDA whether a 3PL should be licensed, the responsibility for determining whether a 3PL meets all applicable requirements and to issue the license remains with FDA (see proposed § 205.6(b)).

So as not to delay the licensure process, when reviewing an application, FDA intends to work with 3PLs to correct minor errors made on the application and communicate with the 3PL about additional information the Agency may need (see proposed § 205.6(c)). When FDA determines that a 3PL facility meets the applicable requirements and that none of the prohibited factors listed in proposed § 205.9(a)(1) are present, FDA will send the applicant an approval letter and a licensing certificate, effective on the date it is issued (see proposed § 205.6(d)).

FDA recognizes that a 3PL may have concerns about what happens to the status of its license if the AO that reviewed its qualifications for licensure has disciplinary sanctions taken against it that affect its approval status or if it is otherwise no longer considered an approved AO. While a 3PL facility should not be penalized for the actions of the AO that reviews its qualifications for licensure, FDA must ensure that the AO's review and findings provide a reliable basis for licensing decisions.

As such, FDA is proposing that the approval status of the AO that performed the licensure review for a 3PL facility will not automatically affect the licensure of a licensed 3PL facility that is otherwise in good standing (see proposed § 205.6(e)). Rather, in the event that an AO has disciplinary sanctions taken against it, ends its business, or is otherwise no longer considered an approved AO, the license of any 3PL facility reviewed by that AO will be subject to appropriate action in accordance with § 205.9 and other applicable statutes or regulations. FDA may verify the 3PL's compliance status and review the facts in that situation to determine the potential effect, if any, on the licensure of 3PL facilities reviewed by that AO.

FDA intends to publish additional guidance regarding the process and procedures related to obtaining and maintaining a 3PL license issued by FDA.

4. Changes to Information, Location, or Ownership of a Licensed 3PL

For the licensing authority to effectively carry out its responsibilities, a 3PL must keep its license information current and report any changes in information, including those that may significantly affect operations such as changes in location or ownership, to the licensing authority. Presently, the reporting requirements for these types of changes vary by State. FDA is proposing in § 205.7 that changes to certain information, including, for example, any changes in information submitted as part of an application for licensure, be submitted electronically to the licensing authority within 30 calendar days of the change (see proposed § 205.7(a)). Additionally, because a license is facility- and-owner specific (see proposed § 205.4(c)), the Agency is proposing that changes in the location or the ownership of a facility will require a new license (see proposed § 205.7(b) and (c)).

5. Expiration and Renewal of Licenses

The DSCSA requires that the regulations establishing national standards for 3PLs provide that a 3PL license expires 3 years after the date of issuance, with the option for renewal for additional 3-year periods (section 584(d)(2)(H) of the FD&C Act). FDA is proposing to implement this requirement under proposed § 205.8 by saying that all 3PL licenses, whether newly issued or renewed by the licensing authority, expire 3 years from the date of issuance or renewal. FDA also proposes that 3PLs may not submit renewal applications more than 90 days prior to the license's date of expiration to ensure that licenses are renewed based on current information. While we do not anticipate lengthy administrative delays by the licensing authority, if a 3PL files an application for a license renewal within the appropriate time period and there is an administrative delay reviewing the license application that causes the 3PL license to lapse, the 3PL will not be penalized for that administrative delay. In this scenario, the 3PL's license will be considered valid during the period of the administrative delay (see proposed § 205.8).

The Agency understands that at the time a final rule covering these proposed national standards goes into effect, there are likely to be 3PLs with existing licenses under State law. Nevertheless, 3PLs with existing State licenses must obtain new licenses in accordance with section 584(a) of the FD&C Act. These national licensing standards serve an important function of ensuring consistency across the domestic market. However, as described above, FDA does not intend to enforce the requirements with respect to the national standards for licensure of 3PLs until 2 years after the regulation is finalized. FDA's proposed requirements are further detailed in proposed § 205.16, which discusses the required inspections prior to licensure.

6. Licensure Denial, Suspension, Reinstatement, and Revocation—Notice and Opportunity To Request a Hearing

The standards for licensure denial are set forth in proposed § 205.9.

Proposed § 205.9(a)(1) enumerates 9 circumstances under which the licensing authority would be required to deny a 3PL's request for licensure or license renewal. FDA believes that this list will help 3PLs focus on good storage practices outlined by FDA that are necessary to protect the integrity of the products in the pharmaceutical distribution supply chain. To avoid

denial or delays of their applications, 3PLs should ensure that they address the reasons for denial of a license outlined in proposed § 205.9(a)(1) when they file for licensure.

Proposed § 205.9(a)(2) details the process afforded to 3PLs whose applications for licensure have been denied. FDA is proposing to provide applicants with the opportunity to provide additional information for reconsideration of the denial. If the licensing authority denies a 3PL's request for licensure after reconsideration, the 3PL will receive a notice of opportunity to request a hearing under existing FDA hearing procedures. FDA requests comment regarding the reconsideration and appeal process outlined in this regulation for 3PLs whose applications for licensure have been denied.

The proposed standards for suspending a 3PL license are set forth in § 205.9(b) and (c) and are based on the severity of risk posed to the public health. Under most circumstances, we anticipate that a 3PL would have the opportunity for a hearing before licensure suspension. However, under certain circumstances that involve repeated conduct detrimental to the public health or refusal to correct significant issues that could lead to the dissemination of illegitimate product, the Agency may suspend a license immediately while giving the 3PL an opportunity to request a hearing. Under proposed § 205.9(b), a 3PL's license may also be suspended after the 3PL receives a notice of opportunity to request a hearing. A suspended 3PL must cease all 3PL activities until their license is re-instated. This provision applies when the licensing authority has a reasonable belief that the 3PL is not in compliance with licensure requirements. FDA is proposing for § 205.9(b) to require the licensing authority to notify the 3PL in writing of the intent to suspend its license. A 3PL will have 30 days from the date listed on the notice of intent to suspend a license to provide additional information to the licensing authority so it may reconsider its decision.

If reconsideration is not sought or is denied, the licensing authority will inform the 3PL in writing of its formal intent to proceed with license suspension. The notice will contain a statement informing the 3PL that it can request a hearing on the question of whether there are sufficient grounds for suspension. The 3PL will have 10 days from the date on the notice to inform the licensing authority of its intent to request a hearing; otherwise the opportunity for a hearing will be waived and the license suspended. FDA believes this process will afford 3PLs a sufficient opportunity to present information and attempt to remedy noncompliance issues which may threaten the safety of products in the supply chain. FDA requests comment regarding this reconsideration and appeal process.

Proposed § 205.9(c) allows for license suspension prior to opportunity for hearing and effective immediately if the 3PL's noncompliance poses an imminent threat to public safety. For example, if a 3PL is warehousing or shipping illegitimate product, and once made aware, corrective actions to protect the public health from the threat of these products are not taken, the 3PL's license could be suspended immediately. Another example could be a scenario where the conditions under which drugs are held or warehoused cause the product to be illegitimate and the 3PL refuses to correct the conditions or continues to ship these illegitimate products. Under the proposed regulation, in such a situation, the licensing authority will inform the 3PL in writing that its license is suspended. The notice will also contain a statement informing the 3PL that it may request a hearing and that a hearing, if granted, will be afforded within 10 days upon the receipt of the 3PL's request for hearing. The 3PL has 10 days from the date on the notice of suspension to request a hearing; otherwise its opportunity for a hearing will be waived. FDA believes that this limits the amount of time a 3PL license would be suspended while providing a reasonable amount of time both for the 3PL to review the notice of suspension and collect the necessary information to demonstrate that its license should not be suspended, and for FDA to consider a request for a hearing and to schedule and prepare for a hearing, if the hearing request is granted. FDA believes immediate suspension of a 3PL license is crucial in cases where continued operation of the 3PL presents an imminent threat to public safety and the pharmaceutical supply chain.

Under proposed § 205.9(d), a 3PL's suspended license may be reinstated if the 3PL can demonstrate to the licensing authority that it is in compliance with regulation requirements.

Under the proposed rule, the process outlined at 21 CFR 10.75 is the default for appeals regarding a denied application for a 3PL license, and the hearing process outlined at 21 CFR part 16 is the default for appeals regarding a suspended or revoked 3PL license. However, the 3PL may request any of the procedures in 21 CFR parts 10 through 16. FDA believes that this proposed approach is consistent with current practice and suggests that States develop comparable processes.

The standards for revoking a 3PL license are set forth in proposed § 205.9(e). The licensing authority will revoke a license if it finds that a 3PL whose license has been suspended is unable or refuses to comply with the licensing requirements. The requirements governing the revocation of a 3PL license are set forth in proposed § 205.9(e)(2) through (5) and mirror those outlined in § 205.9(b)(2) through (7) for licensure suspension, with one exception: When the licensing authority informs the 3PL of its intent to revoke a license, the 3PL is given no opportunity for reconsideration since it already had an opportunity to rectify deficiencies while its license was suspended.

In addition, where a 3PL fails to timely renew its application, the license will be considered expired and a 3PL will need to submit an application for new licensure because the licensing authority may be unable to confirm that the 3PL continues to meet all necessary licensure requirements (see proposed § 205.9(f)).

FDA is also proposing to terminate a 3PL's license upon request from the 3PL when the request includes a notice of the 3PL's intent to discontinue its activities and a waiver of an opportunity for a hearing. The 3PL will be required to apply for a new license should it decide to resume 3PL activities (see proposed § 205.9(g)).

7. Good Storage Practices for 3PL Facilities

The DSCSA charges FDA with creating national standards for the licensure of 3PL facilities, including the requirement that 3PLs comply with storage practices as determined by the Secretary (see section 584(d)(2)(C) of the FD&C Act). Those requirements are detailed in proposed § 205.10. FDA considers the requirement that ''each facility of such [3PL]'' be licensed ''in accordance with the regulations'' (section 584(a) of the FD&C Act) to mean that 3PLs without a facility are not required to be licensed. Section 584 of the FD&C Act provides that FDA will establish licensure standards that include requirements relating to storage of product. These standards address issues regarding access and maintenance that presuppose the existence of a physical facility where product is maintained. As such, the requirements apply to each 3PL facility that is owned, rented, or leased by the 3PL. If the 3PL shares the same name and location as another trading partner

(for example, a wholesale distributor), each entity must be separately licensed and must have separate systems and processes in place for their separate functions (see proposed § 205.10(b)).

The requirements for 3PL facilities regarding how products will be stored and adequate security maintained are set forth in proposed § 205.10(c). This provision includes requirements for storage of nonsaleable products within the 3PL facility. If the facility is in possession of a suspect product, the facility must have clearly defined areas in which to quarantine the suspect product until the product is dispositioned (section 584(d)(2)(C)(i) of the FD&C Act).

FDA is also proposing to require that 3PLs keep illegitimate product and other products unfit for distribution in a clearly defined and designated area, separate from saleable products, until dispositioned so the illegitimate or otherwise unfit product is not inadvertently combined with saleable products (see proposed § 205.10(c)(2)). An illegitimate product poses as great a risk to public health, if not a greater risk, as a suspect product because a product is illegitimate when there is credible evidence shows that the product is counterfeit, diverted, stolen, intentionally adulterated such that the product would result in serious adverse health consequences or death to humans, is the subject of a fraudulent transaction, or appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans (section 581(8) of the FD&C Act). As such, it is counter to public health to store products that are unfit for distribution alongside saleable product. Furthermore, it would be illogical to move suspect product that has been determined to be illegitimate out of quarantine and into another area to be potentially stored with saleable product.

8. Personnel Requirements Necessary for Good Storage Practices

Ensuring that 3PL personnel are appropriately qualified is integral to establishing good storage practices (section 584(d)(2)(C) of the FD&C Act). For this reason, proposed § 205.10(b)(3) requires that a 3PL facility must be designed in such a manner that only personnel who possess appropriate and verifiable experience and training will have access to areas in which products are held. While not proposed to be required in part 205, FDA believes that a best practice in order to maintain the security of prescription drug products, would be for a 3PL to screen personnel who work in areas of its facility where prescription drug products are held for records of Federal or State criminal convictions relating to the possession, control, or distribution of prescription drugs. While also not proposed to be required in part 205, FDA believes it would be a best practice for a firm to request that employees state that they are not engaged in and will not engage in the illegal use of controlled substances while serving in their capacity within the 3PL.

FDA also proposes requiring that 3PLs maintain and make available to the licensing authority certain information about their facilities' managers and designated representatives (see proposed § 205.11). Furthermore, FDA is establishing specific employee qualifications with respect to facility managers or designated representatives that are necessary to effect good storage practices (see proposed § 205.11(b)). Specifically, FDA is proposing to require that a facility manager or designated representative of the facility manager serve in either capacity for only one facility at any one time (see proposed § 205.11(b)(2)). FDA believes that a facility manager or designated representative of the facility manager must be accountable for all operations of a 3PL facility. That facility manager or designated representative must be present within the facility, and must be familiar with the day-to-day operations of that facility. FDA believes that the best way to ensure the accountability and familiarity required for compliance is for a designated representative or facility manager to serve only one facility at a time. This is to ensure that the facility manager or designated representative is actively engaged in managing the daily operations of the facility and that they remain aware of any non-compliance issues that may arise. To ensure the qualified designated representative can fulfill their obligations to manage and carry out daily operations, FDA proposes to require that a 3PL provide its designated representative with adequate authority and the necessary resources (see proposed § 205.11(c) and (d)). FDA believes that establishing these requirements will help ensure that the products handled by a 3PL are properly safeguarded to protect the supply chain and the public health.

Section 584(d)(2)(E) and (F) of the FD&C Act requires mandatory background checks for facility managers or the designated representatives of facility managers to ensure that neither the 3PL's facility manager nor the designated representative has engaged in the prohibited behaviors outlined in proposed § 205.11(e). Additionally, FDA is outlining other activities which may lead to the denial of licensure in proposed § 205.11(f). They are not bars to licensure, but they are factors that may be considered by licensure authorities when reviewing an application for licensure to determine whether the 3PL has storage practices sufficient to maintain adequate security over the facility. FDA requests comment on this section of the regulation and the scenarios outlined therein.

Requiring that individuals with significant authority over 3PL activities be subject to a criminal background check adds an additional layer of safety and security to the supply chain (see proposed § 205.11(g)). Theft of product by personnel who have direct access to areas where products are stored is a known problem across the healthcare industry; the background checks required by section 584(d)(2)(F) of the FD&C Act that FDA is proposing here are necessary precautions to prevent the potential theft, loss, or abuse of prescription drugs.

FDA suggests an additional best practice for a 3PL to utilize when staffing their operation. This best practice, related to staff who work within a 3PL, is designed to ensure security within a 3PL. FDA recommends to 3PLs that the individuals who work within their operation and have access to prescription drugs should not have a record of criminal activity involving violations of the FD&C Act or other laws involving prescription drugs.

When screening personnel who work in areas of a 3PL facility where products are held, including the facility manager or designated representative, FDA recommends that a 3PL consider whether such personnel have (1) engaged in a pattern of violating the requirements of section 584 of the FD&C Act that present a threat of serious adverse health consequences or death to humans; (2) been found to have committed or facilitated commission of any prohibited acts under the FD&C Act or violated or facilitated any violations of any of the regulations in this part or analogous provisions of the State licensing authority, as applicable; (3) been convicted of any violation of Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, distribution of controlled substances, or third-party logistics services; or (4) been convicted of any felony under Federal, State, or local laws involving or related to prescription drugs. FDA believes that 3PLs should consider an applicant's history of violations of the FD&C Act, or other

laws involving prescription drugs, when making staffing decisions.

9. Required Written Policies and Procedures

Section 584(d)(2)(C)(iii) of the FD&C Act enumerates certain types of written policies and procedures that FDA regulations must require, and tasks FDA with defining the content with more specificity. Those written policies and procedures are set out in proposed § 205.12. All 3PLs would be expected to establish, maintain, and follow the written policies and procedures set forth in these proposed subsections for each 3PL facility, to the extent that the requirements of those sections are relevant to the scope of their specific 3PL activities. Under the proposed regulation, all written policies and procedures will be made available to the licensing authority upon request, and the licensing authority will be permitted to have access to and copy records of the 3PL to ensure that the 3PL facility is following its written policies and procedures (see proposed § 205.12(a)). Written policies and procedures include those that are stored and maintained electronically.

FDA is implementing the statutory requirements listed in section 584(d)(2)(C)(iii) of the FD&C Act through proposed § 205.12(c)(1) through (6). Under these requirements, 3PLs must maintain written policies and procedures to address a product's receipt, security, storage, inventory, shipment, and distribution. Proposed § 205.12(c)(1) through (6) details the specific elements that such written policies and procedures must contain. Such elements are necessary to maintain supply chain integrity and align with current industry practices to protect the integrity of the drugs that are distributed through the supply chain.

To ensure good storage practices, FDA is also proposing to require that 3PLs establish written policies and procedures for handling not only expired product as required in section 584(d)(2)(C)(iii)(VI) of the FD&C Act, but also products that are unfit for distribution (see proposed § 205.12(f)). Furthermore, any drug unfit for distribution should be segregated and returned or destroyed to prevent its distribution to the patient (see proposed § 205.12(f)(1)). These requirements will ensure that drugs, the distribution of which would violate the FD&C Act and which may not be fit for consumption by American consumers for a variety of reasons, are not distributed into the supply chain. FDA believes that these proposed standards align with current industry practices.

Similarly, to further ensure the safety and efficacy of drug products, FDA is proposing that 3PLs maintain written policies and procedures related to the storage, inventory, and disposition of both suspect and illegitimate products. In the case of a suspect product, the written policies and procedures must include the procedure for quarantine or destruction of the product if directed to do so by the product's manufacturer, wholesale distributor, dispenser, or an authorized government agency. In the instance of an illegitimate product, written policies and procedures must be in place to ensure that illegitimate product is appropriately dispositioned as directed by the respective manufacturer, wholesale distributor, dispenser, or authorized government agency. This may include segregation in a clearly defined, designated area from which the product may be dispositioned. FDA believes that these proposed standards align with current industry practices and will give 3PLs a clear roadmap for dealing with potentially difficult situations involving suspect and illegitimate product.

Finally, FDA views it as a best practice for a 3PL to establish written policies and procedures to ensure that it only engages in 3PL activities on behalf of authorized trading partners with respect to a product. DSCSA requires that all other entities that accept or transfer direct possession or ownership in the supply chain are only permitted to do business with other authorized trading partners (section 582 of the FD&C Act). FDA believes that, to further ensure supply chain security and integrity, it is important that 3PLs also only do business with other authorized trading partners. 3PLs that engage in transactions with non-authorized trading partners may expose the supply chain to potentially harmful or substandard product. FDA notes that 3PLs are included in the wholesale distributor and third-party logistics provider reporting public database (available at *https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm*) which allows manufacturers, wholesale distributors, repackagers, and dispensers to determine if the 3PL is authorized. Similarly, 3PLs should include using the publicly available information regarding other trading partners in their written policies and procedures to ensure they are doing business with only authorized trading partners.

10. Recordkeeping and List of Trading Partners

The maintenance, availability, and accuracy of the records made available for inspection under section 584(d)(2)(D) of the FD&C Act is critical to demonstrate that 3PLs are acting in compliance with relevant laws and regulations and to ensure their records can be relied upon to identify any potential risk to the public health. As such, FDA is proposing to require that all records be securely stored, with procedures in place to restrict access and protect record integrity, and that any alterations made to records be signed and dated while preserving the original information contained in the record (see proposed § 205.13(a)). These records can be stored and maintained electronically. These records maintenance requirements will allow for greater confidence in both the information that is preserved at the facility and the information potentially disseminated to other trading partners.

FDA is proposing that all records must be retained for a minimum of 3 years, except for records related to suspect and illegitimate products, product quality complaints, and destroyed, returned, and recalled products, which each must be retained for a minimum of 6 years (see proposed § 205.13(b)). Such record retention is necessary not only to ensure 3PLs are complying with the FD&C Act, but also to ensure that there is consistency and continuity in the access to the information across the records required pursuant to sections 582, 583, and 584 of the FD&C Act. The DSCSA requires that, upon the licensing authority's request, 3PLs provide the licensing authority with a list of the trading partners (manufacturers, wholesale distributors, and dispensers) for which the 3PL conducts 3PL activities (section 584(d)(2)(G) of the FD&C Act). This requirement would be codified in proposed § 205.14 and would also include repackagers for which the 3PL provides services when those repackagers are acting on behalf of a manufacturer, wholesale distributor, or dispenser of a product, as explained in the definition of *other logistics services* at § 205.3(i).

11. Annual and Other Reporting to FDA

Under DSCSA, 3PLs must report certain information to FDA to be considered an authorized trading partner (sections 581(2)(C) and 584(b) of the FD&C Act). The annual reporting requirements for 3PLs went into effect on November 27, 2014. Proposed § 205.15 clarifies the statutorily

prescribed annual reporting requirements and proposes the collection of additional information to provide complete and useful information about 3PLs that can be used by FDA, States, and trading partners.

The DSCSA requires 3PLs to report to FDA for each facility: (1) The State by which the facility is licensed; (2) the facility's license number; (3) the facility's name and address; and (4) all trade names under which the facility conducts business (section 584(b) of the FD&C Act). If a facility conducts more than one type of activity, such as 3PL activities and wholesale distribution activities, the facility must be licensed as both a wholesale distributor and a 3PL and must report to FDA separately as a wholesale distributor and a 3PL (section 503(e)(2) of the FD&C Act).

FDA is proposing to require that 3PLs use an electronic system provided by FDA for reporting (see proposed § 205.15(a)). This electronic system will increase efficiency by providing uniformity in the content and format of reports, thereby making the information easier to process. FDA is proposing that the annual reporting schedule require all 3PLs to report each calendar year between January 1st and March 31st, although an entity may update information at any time (see proposed § 205.15(b)). For example, if a 3PL chooses to update a license on December 15, 2019, that 3PL will still have to report during the January 1, 2020 through March 31, 2020 annual reporting period.

The specific information that 3PLs must electronically report to FDA is set forth in proposed § 205.15(c). The DSCSA requires that 3PLs report the name and address of each facility (section 584(b)(2) of the FD&C Act). In fulfilling this requirement, the 3PL must provide the address that is associated with the State or Federal license. Licensed entities are also required to report to FDA the State by which they are licensed and the license number (section 584(b)(1) of the FD&C Act). In addition, FDA is proposing to require that the reported company name be identical to the official company name appearing on the license (see proposed § 205.15(c)(2)). Maintaining an account in FDA's electronic system for each 3PL facility license during the reporting period is integral to FDA's ability to provide oversight, as each facility of a 3PL must be licensed in order for the 3PL to conduct 3PL activities.

In addition to the requirements specified in the statute, FDA is proposing to require an additional data element that FDA views as important to the Agency, the States, and trading partners. This additional information will inform other trading partners that the 3PL is in fact an authorized trading partner with whom they can do business. To this end, FDA is proposing to require that 3PLs provide the date each State license expires. This information is essential for determining that licensure status for each 3PL facility is current.

Also, in addition to the physical address, which is required to be reported by statute, FDA believes that it would be a best practice for 3PLs to submit a unique facility identifier (UFI) that corresponds with the facility name and facility address. The UFI for a 3PL facility is useful to FDA when identifying and confirming certain business information. To be most helpful to FDA and other trading partners, a 3PL should obtain a separate UFI for each *physical* address that the 3PL is reporting since each 3PL facility must meet the 3PL requirements, and licensure is facility specific. FDA also believes that it would be a best practice for 3PLs to submit the contact information of an individual who will interact with FDA, including that individual's name, telephone number, and email address. FDA recommends as a best practice that the 3PL designate a contact person who is familiar with the daily operations of the 3PL facility, such as the designated representative, to ensure efficient processing of inquiries and minimize the impact inquiries may have on the daily operations of the facility.

It is important for other trading partners and FDA to know whether a 3PL has had a license revoked or suspended or whether a 3PL has had any other significant disciplinary actions taken against them that limits the ability of a facility to conduct drug-related business. As such, 3PLs must report significant disciplinary actions to FDA. This will involve providing a DEA registration number or State controlled substance license number when there is a significant disciplinary action issued by the DEA or the State controlled substance licensing authority that would limit the ability of the 3PL facility to conduct 3PL activities related to the distribution of controlled drug substances that meet the definition of product, as defined at § 205.3(k). In such a situation, information about the DEA registration or State controlled substance license is important because the disciplinary action would likely be associated with that specific license or registration.

A *significant disciplinary action* is defined in the proposed regulation as an action that limits the ability of a facility to conduct 3PL activities related to the distribution of prescription drug products. FDA proposes that, within 30 calendar days after a significant disciplinary action is imposed or taken by a State or Federal government, 3PLs must report the type of disciplinary action, the date the action was taken, and the State where the disciplinary action occurred, as well as submit any documents associated with the disciplinary action, including a final ruling by the relevant State or Federal agency or board or a consent decree.

Finally, FDA is proposing to require a 3PL to report to FDA within 30 calendar days of ceasing warehousing or other logistics services that it is going out of business or voluntarily withdrawing a 3PL license from a State. FDA believes reporting this information is essential for the information in the public database to be complete, accurate, and useful for FDA, the States, and trading partners.

To ensure efficient enforcement of FD&C Act requirements and to make public the voluntary information provided by each 3PL facility, FDA proposes adding 3PL licensure to the public database to make information about 3PLs available on FDA's website. Having the license status of 3PLs in one publicly available database will help FDA, trading partners, and other stakeholders determine whether 3PLs are properly licensed and authorized.

12. Inspection Provisions

Section 584(d)(2)(D) of the FD&C Act requires that the regulations provide for periodic inspections of 3PL facilities to ensure compliance with the national standards and directs FDA to determine the intervals at which periodic inspections of a 3PL will be conducted by the licensing authority to ensure a facility's compliance with the law and this regulation. To this end, FDA is proposing to require that a physical inspection of a 3PL facility be conducted prior to issuance of the initial license and routinely once every 3 years thereafter (see proposed § 205.16(a) and (b)). The regulation proposes allowing the licensing authority, or an AO, as determined by the licensing authority, to conduct physical inspections (see proposed § 205.16(a)). As used in part 205, subparts A and B, *licensing authority* means the State licensing authority or FDA. When developing the timeframes for inspections, FDA sought to balance the risk to the supply chain while considering FDA's and State agencies' resource constraints. FDA is proposing to require that the physical inspection of a 3PL facility warehouse space include

the paper and electronically stored records detailing the processes related to all 3PL activities (see proposed § 205.16(c)). FDA has authority to require that an inspection of a 3PL warehouse include the 3PL's records, files, and processes related to product warehousing. Section 704(a)(1) of the FD&C Act (21 U.S.C. 374(a)(1)) states that ''in the case of any . . . warehouse . . . in which prescription drugs . . . are held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities).'' This authority directly applies to FDA's ability to inspect a 3PL's facility warehouse space for relevant records and files to ensure compliance with the FD&C Act. FDA also proposes to require that 3PLs permit inspections at reasonable times and that the licensing authority conduct its inspection in a reasonable manner (see proposed § 205.16(c) and (d)).

D. Approved Organizations for 3PLs

1. Approval and Utilization of Outside Organizations in the Licensure Process

The DSCSA requires that regulations codified by FDA establish a process by which a third-party organization approved by FDA shall, upon a 3PL's request, ''issue a license'' to each 3PL facility that meets the requirements for licensure (section 584(d)(2)(A) of the FD&C Act). However, in situations where a State has not established a licensure program in accordance with the regulations, the DSCSA charges FDA with issuing 3PL licenses, provided the applicable requirements for licensure are met (section 584(a)(1)(B) of the FD&C Act). Accordingly, FDA interprets the language of 584(d)(2)(A) of the FD&C Act to mean that a third-party organization approved by FDA—an AO—will conduct a review of the 3PL's qualifications for licensure and issue a report to FDA regarding whether the 3PL ''demonstrates that all applicable requirements for licensure . . . are met,'' which FDA can rely on when issuing a license per section 584(e) of the FD&C Act.

The DSCSA allows States and FDA to approve organizations for purposes of licensure review and periodic inspection. Proposed §§ 205.17, 205.18, and 205.19 contain the process that FDA will use to approve organizations and the qualifications to become an AO. FDA suggests that States that choose to rely on AOs for licensure reviews have in place the same or similar processes for approved organizations to conduct licensure reviews and for decisions affecting the approval status of those organizations.

The scope of work AOs would be tasked with performing and the standards an AO must meet to become approved are detailed in subpart B of proposed part 205. The proposed rules also set forth the process by which FDA will approve organizations to review the qualifications of 3PL facilities for licensure, which we refer to as a ''licensure review.''

A licensure review consists of performing a review of all documents submitted to the licensing authority in support of an application for 3PL licensure and conducting an inspection of the facility as directed by the licensing authority. If a review of documentation supports licensure of the 3PL facility, the facility will then be inspected by an AO, as directed by FDA. FDA is proposing that the AO's licensure review be completed within 90 days upon receiving notice from the Agency to conduct the licensure review. FDA believes that this 90-day timeframe is sufficient for an AO to perform the work with which they are tasked while also ensuring that there are no undue delays in the licensure process. Upon completion of the licensure review, the AO would then provide FDA with a licensure review report within 7 days (see proposed § 205.17(b)), with a copy sent to the 3PL facility. As proposed, using the report submitted by the AO, FDA would make the final determination as to whether a 3PL facility should be issued a license. The process that AOs should follow when conducting routine inspections of 3PL facilities mirrors the process for licensure review and is detailed in proposed § 205.17(c).

It is important that FDA can verify an AO's continued compliance with the approval requirements. Therefore, to keep its approval, FDA is proposing to require that an AO maintain certain records for a period of at least 5 years and these records must be readily available to FDA upon request. Unless specified by statute, we believe it is reasonable for the required length of maintenance of records to align with the length of the entity's licensure term. In addition, to ensure public safety, FDA is proposing to require that AOs report potential violations at 3PL facilities to FDA within 24 hours of discovery (see proposed § 205.17(f)). The general qualifications for approval of AOs are set out in proposed § 205.18.

To become and remain approved, FDA is proposing to require that an organization, and those employed by the organization, abide by certain requirements that are intended to secure against conflicts of interest, promote professional business practices, and protect non-public information (see proposed § 205.18(a)).

FDA is proposing to allow AOs to hire outside contractors to conduct licensure reviews or licensure review-related activities. Under FDA's proposed regulation, AOs who decide to use outside contractors must ensure that the contractors not only effectively carry out the licensure review or licensure review-related activities in a manner consistent with this proposed regulation to ensure public health, but the AO must also ensure that the contractors properly protect all non-public information.

For an AO to maintain approval, FDA proposes to require that the AO ensures contractors abide by all applicable confidentiality agreements, that the AOs have policies and procedures in place to ensure the contractors abide by these proposed standards, and that the contractors have the necessary training and expertise to carry out licensure reviews (see proposed § 205.18(b)(1)). Also, before a contractor hired by an AO may perform a licensure review of a 3PL facility, the 3PL must have entered into an agreement with the AO giving the AO permission to share with contractors the 3PL's confidential commercial information (see proposed § 205.18(b)(2)). If such consent is not provided by the 3PL facility, the AO must perform the licensure review itself. FDA believes that this approach is reasonable given that it is the AO's decision to work with contractors and, under this proposed regulation, the ultimate responsibility for the licensure review rests with the AO.

In addition, so FDA may keep track of which organization is responsible for each licensure review, FDA proposes that AOs must submit to FDA a list of the contractors used by the organization each year and the AO must certify that such contractors comply with the applicable requirements (see proposed § 205.18(b)(3)). Finally, to ensure that the standards set forth in this regulation are followed and that lines of responsibility are clear, FDA proposes to require that the AOs remain responsible for all the work performed by outside contractors (see proposed § 205.18(b)).

FDA proposes to prohibit contractors from subcontracting licensure review or licensure review-related activities (see proposed § 205.18(b)(1)(ii)). Limiting the ability of contractors to further delegate their responsibility ensures that FDA will have accurate information about who is conducting licensure reviews, that those responsible for the licensure reviews have the necessary

qualifications, and that their conduct is governed by this proposed regulation.

The proposed process that FDA will use to approve organizations, including the application process, as well as the process for suspending or revoking an organization's approval, are set forth in proposed § 205.19. To ensure compliance with DSCSA, FDA is proposing that organizations seeking approval by FDA must first electronically submit to FDA an application demonstrating the organization's ability to assess compliance with all 3PL requirements detailed in proposed § 205.19 (see proposed § 205.19(a) and (b)). Organizations must also provide training that their employees must pass before they may conduct licensure reviews (see proposed § 205.19(c)). To verify information contained in the application and further ensure compliance with the proposed regulation, FDA proposes that, before an AO may conduct its first licensing review, it must be audited by FDA (see proposed § 205.19(d)). A new approval will be valid for 5 years (see proposed § 205.19(e)).

If an organization's request for approval is denied, the organization may issue a request for reconsideration under 21 CFR 10.75 (see proposed § 205.19(f)). In addition, to ensure compliance and protect public health, FDA proposes that an AO may have its approval suspended if it does not maintain the standards outlined in this part (see proposed § 205.19(g)). A suspended AO must cease all 3PL licensure review including any pending inspections of 3PL facilities. A suspended AO must notify any 3PLs under a pending licensure review by the AO, of the AO's suspension within 7 calendar days (see proposed § 205.19(g)(5)). While most suspensions will happen only after notice and opportunity to request a hearing, under the proposed regulations, FDA reserves the ability to suspend approval prior to a hearing if there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans (see proposed § 205.19(h)).

Furthermore, FDA proposes that a suspended approval can be reinstated if the issue is resolved within 1 year from the date of suspension (see proposed § 205.19(i)), though it may be revoked if the organization fails to rectify the situation that resulted in the suspension (see proposed § 205.19(j)). FDA believes that 1 year provides the AO enough time to remedy most situations. An AO's approval may also be reinstated on a conditional basis. If the AO is conditionally reinstated, they will enter a three-year probationary period, during which if any material deficiencies arise, their license will be subject to immediate revocation (see proposed § 205.19(i)(2)).

FDA also proposes to permit an AO to voluntarily withdraw its approval, but it must inform FDA of any facilities with pending reviews (see proposed § 205.19(l)). To further ensure that pending licensure reviews are not overlooked, under FDA's proposed regulation, an AO whose approval has been suspended, revoked, or voluntarily withdrawn has the responsibility to report this information to those 3PL facilities with pending licensure reviews (see proposed § 205.19(m)); this will stop the clock on the 90-day licensure review while the 3PL applies for licensure review from another AO or FDA. Also, to ensure that the AOs continue to meet the standards put forth in this subpart, and part 205 generally, under the proposed regulations, an AO must inform FDA of any changes to information that was submitted as part of its application for approval (see proposed § 205.19(n)(1)). Since the approval of an organization is nontransferable, changes in ownership also require an AO to submit a new application to FDA (see proposed § 205.19(n)(2)). Finally, as an additional assurance that an AO continues to comply with the provisions of this part, FDA proposes to require that AO's remain subject to periodic audits by FDA (see proposed § 205.19(o)).

E. National Standards for Wholesale Distributors

1. Requirement That Wholesale Distributors Be Licensed

To implement section 503(e)(1) of the FD&C Act, FDA is proposing to codify at § 205.20(a) the requirement that a wholesale distributor be licensed by the State from which the drug is distributed, or by FDA if the State from which the drug is distributed has not established a licensure requirement in accordance with the standards proposed herein, as well as by the State into which the drug is distributed if that State requires such a license. This requirement is consistent with how States currently license wholesale distributors.

FDA anticipates that, for the purposes of annual reporting, a wholesale distributor who maintains multiple licenses to engage in wholesale distribution, will be able to report their required information aggregately for all their licenses (section 503(e)(2) of the FD&C Act). FDA believes this approach will increase efficiency for both wholesale distributors and the Agency, ensure that licenses for wholesale distribution facilities will be granted to qualified firms, and ensure records related to their facilities will be maintained in an organized fashion.

In addition, FDA proposes to set the licensure term for wholesale distributors at 2 years (see proposed § 205.20(b)). FDA considered current State requirements, as well as the potential impacts on State and Agency resources, to determine the term for licensure. Ultimately, the Agency believes that 2 years aligns with current practices, does not place an undue burden on State or FDA resources, and provides adequate protection to American consumers because it ensures that renewals will be based on current information and operations.

2. Surety Bonds

Wholesale distributors are required to obtain a surety bond to be licensed and engage in wholesale distribution (section 583(b)(3) of the FD&C Act). FDA is proposing to establish the terms of this requirement in proposed § 205.21. To receive or renew a license, a surety bond of $100,000, or $25,000 if applicable (for wholesale distributors with annual gross receipts of $10,000,000 or less), must be in place at the time the wholesale distributor's application for licensure or licensure renewal is submitted to the licensing authority (see proposed § 205.21(b)). The surety bond is intended to ensure compliance with DSCSA and that any administrative penalties levied by the licensing authorities are paid. DSCSA also permits the furnishing of ''other equivalent means of security acceptable to the State'' in lieu of a bond (section 583(b)(3)(A)(i) of the FD&C Act). It would be up to the State licensing authority to determine what, if anything, would constitute an equivalent means of security to a surety bond. Where FDA is the licensor, the wholesale distributor would need to furnish a surety bond to satisfy the bond requirement as other equivalent means of security appear to be specifically reserved for the States.

While a bond is required before a wholesale distributor may acquire the necessary license, section 583(b)(3)(B) of the FD&C Act provides a set of circumstances under which the surety bond requirement will be waived. FDA is proposing to codify at § 205.21(b)(3) the DSCSA requirement that if a wholesale distributor can prove it has the necessary bond for the State where the facility is located (*e.g.,* by providing a copy of the existing security bond

agreement), the requirement for an additional surety bond for another State is waived. In this situation, the wholesale distributor does not have to acquire an additional bond to satisfy the non-resident licensure requirements of the State into which the wholesale distributor plans to distribute. However, it remains unclear if and how this waiver should apply when an equivalent means of security to the surety bond are used. FDA requests comment specifically related to the waiver to the surety bond requirement and whether that waiver should apply to scenarios where some other equivalent means of security is used in lieu of a surety bond.

The terms that a surety bond must include are outlined in proposed § 205.21(c). FDA proposes to require not only that the terms cover the liability requirements related to administrative penalties, but also that the bond remain in full force for 1 year after the license expires and that the surety company guarantee payment within 30 days of receiving notice from the licensing authority. FDA also proposes permitting licensing authorities to make claims against the surety bond for 1 year after the wholesale distributor's license expires or within 60 days after an administrative or legal proceeding has concluded, whichever is longer. These timeframes seek to ensure that the rights of the different parties involved in a potential claim will be adequately protected. This is particularly important with respect to the waiver because it allows the affected States equal access to the surety bond and ensures consistent standards across States.

The implications of termination or lapse in coverage of a surety bond are detailed in proposed § 205.21(d). A wholesale distributor may cancel its surety bond, but FDA proposes to require that it give all impacted licensing authorities 30 days' prior notice before such cancellation take effect. Such notice is necessary because a wholesale distributor's license will be suspended upon the cancellation of the surety bond unless the wholesale distributor acquires a new bond before to the old bond is cancelled. FDA proposes that a license will be suspended if a licensing authority discovers a lapse in bond coverage.

FDA also proposes to require that the surety bond permit actions to be brought by either a State or Federal licensing authority (see proposed § 205.21(e)), provide the contact information for the surety company (see proposed § 205.21(f)), and name the specific parties to the surety bond (see proposed § 205.21(h)).

3. General Requirements for Licensure

This section includes the requirements for the application. FDA notes that the applicant would have to demonstrate compliance with the requirements as set forth in subpart C, including a satisfactory inspection, as described in proposed § 205.28, and criminal background checks for facility managers and designated representatives, as described in proposed § 205.25, to be granted a wholesale distributor license.

The general application requirements that must be met for a State or Federal licensing authority to issue a wholesale distributor license are set forth in proposed § 205.22. The requirements applicable to the individual who submits the licensure application are detailed in proposed § 205.22(a). FDA proposes to require that the applicant submit all required information and pay a licensing fee in order to be considered for licensure. FDA believes these general requirements align with current industry practices.

FDA is proposing at § 205.22(b) to require that the applicant provide the surety bond or other equivalent means of security acceptable to the State, required by section 583(b)(3) of the FD&C Act and detailed in proposed § 205.21, as part of the wholesale distributor's application for a license.

The information that the licensing authority will require as part of a wholesale distributor's initial application for licensure and renewal applications is set forth in proposed § 205.22(c) and (d). This information is necessary for the licensing authority to assess whether the wholesale distributor is in good standing and has the infrastructure and capabilities to fulfill the duties and obligations of licensure. For example, FDA is proposing to require that a wholesale distributor inform FDA if it has received any citations for violating requirements for licensure or received any significant disciplinary actions within the past 7 years (see proposed § 205.22(c)(8)). FDA believes this information is necessary to ensure the wholesale distributor can demonstrate that it has not engaged in a pattern of violating the standards for licensure. The DSCSA defines prohibited persons, in part, as licensees who have ''engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans'' (section 583(d) of the FD&C Act). Therefore, this information is necessary to demonstrate that a wholesale distributor is not prohibited from receiving or maintaining licensure for wholesale distribution.

Finally, FDA proposes to require that a wholesale distributor's license be readily retrievable at the facility, and that the facility permit State or Federal inspectors, or others acting on behalf of the licensing authority, to inspect the license (see proposed § 205.22(e)).

4. The Federal Licensure Process

Section 503(e) of the FD&C Act, as amended by DSCSA, requires FDA to license wholesale distributors directly if the State in which it engages in wholesale distribution has not established a licensing requirement (section 503(e)(1) of the FD&C Act). Proposed § 205.23 details the process that FDA will use when issuing licenses to wholesale distributors. While this section is only applicable to wholesale distributors obtaining a license from FDA, FDA suggests States implement similar procedures to ensure that all wholesale distributor licenses issued are consistent with the proposed regulation pursuant to section 503(e)(1)(B) of the FD&C Act. FDA plans to make information available to clarify who is the appropriate licensing authority in the wholesale distributor's State. FDA believes this streamlined process for application will allow for greater clarity and harmonization across the industry.

For wholesale distributor license applications submitted to FDA, FDA proposes that the wholesale distributor submit the application electronically, including the information outlined in proposed §§ 205.21 and 205.22, along with additional supporting documentation (see proposed § 205.23(a)(1)). The DSCSA authorizes FDA's use of third-party organizations—AOs—to conduct inspections of wholesale distributors required under section 583(c) of the FD&C Act. If FDA has approved one or more AOs to inspect wholesale distributors, the wholesale distributor should note the AO it prefers to conduct its inspection on the application submitted to FDA (see proposed § 205.23(a)(2)). If no AO has been approved, FDA will conduct the inspection (see proposed § 205.23(a)(3)). Furthermore, submission of the application to FDA will not be considered complete until FDA receives all pertinent information and fees (see proposed § 205.23(a)(5)).

While the DSCSA permits AOs to conduct inspections of wholesale distributors applying for licensure, the responsibility of determining whether a wholesale distributor meets all the applicable requirements set forth in this proposed regulation remains with FDA (see proposed § 205.23(b)). To avoid

delays in the licensure process, FDA intends to work with wholesale distributors to correct minor errors made on the application (*e.g.,* missing written policies and procedures) and communicate with the wholesale distributor about additional information the Agency may need to process and review the application (see proposed § 205.23(c)). If the wholesale distributor meets the requirements outlined in this proposed part and none of the prohibited factors listed in proposed § 205.30(a)(1) are present, FDA will approve the application and send an approval letter and license certificate (see proposed § 205.23(d)).

FDA recognizes that a wholesale distributor may have concerns about what happens to the status of its license if disciplinary sanctions are taken against the approval status of the AO that conducted its inspection when applying for licensure or if the organization is otherwise no longer considered an approved AO. While FDA believes that a wholesale distributor should not be penalized for the actions of the AO, FDA must ensure that the AO's review and findings provide a reliable basis for licensing decisions. As such, FDA is proposing that, if the wholesale distributor is otherwise in good standing, a change in the approval status of the AO that conducted the inspection of the wholesale distributor will not automatically affect the licensure of a licensed wholesale distributor (see proposed § 205.23(e)). Rather, in the event that an AO has disciplinary sanctions taken against it, ends its business, or is otherwise no longer considered an approved AO, the license of any wholesale distributor reviewed by that AO will be subject to appropriate action in accordance with § 205.30 and other applicable statutes or regulations. FDA may verify the wholesale distributor's compliance status and review the facts in that situation to determine the potential effect, if any, on the licensure of wholesale distributors inspected by that AO.

5. Changes to Information, Ownership, or Location of Licensed Wholesale Distributors

FDA recognizes that information about a business can change over time. However, for the licensing authority to effectively carry out its responsibilities, license information must remain current and changes in information previously submitted must be reported to the licensing authority. Currently, the reporting requirements for these types of changes vary by State. FDA is proposing the establishment of specific timeframes for reporting changes (see proposed § 205.24) and believes that standardizing the timeframes will help make reporting business-related changes less burdensome for industry and licensing authorities. FDA is proposing that the wholesale distributor submit changes to certain information, such as the information submitted with a surety bond or as part of an application for licensure, to the licensing authority within 30 calendar days of the date the change became effective (see proposed § 205.24(a)). Significant changes, such as changes in location or changes to the person engaged in wholesale distribution, require the added scrutiny that comes with an inspection or review of an application for a new license to ensure that the entity will be able to continue to meet the standards for licensure in its new location or under its new management. For this reason, FDA is proposing that changes in location or changes to the person engaged in wholesale distribution will require an inspection or new license (see proposed § 205.24(b) and (c)). FDA recognizes that the ownership of a facility from which a wholesale distributor leases the facility and conducts wholesale distribution may change without the wholesale distribution operation changing in any meaningful way. If that change does not impact the wholesale distribution operation, the wholesale distributor will not need to apply for a new license. As described in proposed § 205.24(b)(1), the date the change of location takes place is the date the new location begins receiving prescription drugs.

6. Prohibited Persons and Qualifications for Key Personnel

The FD&C Act, as amended by DSCSA, requires FDA to establish and implement standards for the qualifications of wholesale distributors' key personnel (section 583(b)(5) of the FD&C Act). As discussed above and proposed at § 205.3(g), FDA considers key personnel to include individuals with responsibility for managing the operations of the wholesale distributor, including any principal, owner, director, officer of the wholesale distributor, facility manager or designated representative, or other individuals who are authorized to enter into areas where prescription drugs are held and are likely to handle those prescription drugs as a part of their responsibilities within the operation. FDA believes the qualifications for key personnel proposed in § 205.25 are necessary to ensure that all the individuals who are responsible for operating the wholesale distributor's facility are appropriately qualified to carry out their duties and that the wholesale distributor meets the national standards.

Proposed § 205.25(a) lists conduct that prohibits a wholesale distributor from obtaining licensure. Proposed § 205.25(b) establishes the basic standards for key personnel working within a wholesale distribution facility. Key personnel must have the appropriate education, background, training, and experience necessary to carry out their assigned functions within the operation. No one within the facility should carry out the responsibilities of key personnel without the proper training and expertise.

As a part of FDA's responsibility to establish and implement standards for the qualifications of wholesale distributors' key personnel, FDA is proposing that wholesale distributors and their key personnel meet certain other qualifications. Licensure may be denied if a wholesale distributor or any of their key personnel do not meet the standards for qualification as outlined in proposed § 205.25(c).

Key personnel working for a wholesale distributor hold critical positions of trust for protecting the security of the prescription drug supply chain. FDA believes it would be a best practice for a firm to require that all employees not engage in the illegal use of controlled substances while serving in their capacity in the wholesale distribution operation and request that all employees so state.

FDA is proposing to require wholesale distributors to establish and implement written policies and procedures to ensure that their key personnel meet the qualifications contained in this proposed section (see proposed § 205.25(e)) and to maintain certain information about their key personnel that demonstrates they are qualified to carry out the duties assigned to them (see proposed § 205.25(b)), including having the proper education and training (see proposed § 205.25(e)(3)). Proposed § 205.25(f) also limits a facility manager or designated representative to hold that position at one facility at a time. This is to ensure that the facility manager or designated representative is actively engaged in managing the daily operations of the facility and that they remain aware of any non-compliance issues that may arise.

The FD&C Act, as amended by DSCSA, specifically requires licensure standards to include mandatory background checks and fingerprinting of wholesale distributor facility managers and their designated representatives

(section 583(b)(4) of the FD&C Act). Entrusting individuals with the responsibility of distributing prescription drugs prior to a criminal background check may jeopardize the integrity of the drug supply chain and leave the public exposed to unnecessary harm posed by the possible introduction of drugs that are unsafe. FDA is proposing to codify at § 205.25(g) the requirement for facility managers and their designated representatives to submit a full set of fingerprints to conduct local and national criminal background checks. The background check, when completed, must demonstrate that the facility manager or designated representative has no history of criminal convictions pursuant to proposed § 205.25(a).

FDA suggests, when a wholesale distributor staffs its operation, it is a best practice that the individuals who work within their operation and have access to prescription drugs not have a record of criminal activity involving violations of the FD&C Act or other laws involving prescription drugs. This best practice is recommended to help ensure security within a wholesale distributor.

When screening personnel who work in areas of a facility where prescription drugs are held, including the facility manager or designated representative, FDA recommends that a wholesale distributor consider whether such personnel have (1) engaged in a pattern of violating the requirements of section 583 of the FD&C Act that present a threat of serious adverse health consequences or death to humans; (2) been found to have committed or facilitated commission of any prohibited acts under the FD&C Act or violated or facilitated any violations of any of the regulations in this part or analogous provisions of the State licensing authority, as applicable; (3) been convicted of any violation Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, distribution of controlled substances, or 3PL services; or (4) been convicted of any felony under Federal, State, or local laws involving or related to prescription drugs. FDA believes that wholesale distributors should consider an applicant's history of violations of the FD&C Act or other laws involving prescription drugs when making staffing decisions.

7. Wholesale Distributor Storage and Handling of Prescription Drugs, and Required Policies and Procedures

The DSCSA charges FDA with creating national standards for the storage and handling of prescription drugs by wholesale distributors, including facility requirements (section 583(b)(1) of the FD&C Act). To ensure confidence that the prescription drug delivered maintains its quality and integrity throughout the distribution process, FDA believes that wholesale distributors should establish and maintain quality systems that encompass the organizational structure, account for potential vulnerabilities or threats to the systems, and clearly articulate the procedures and processes for all wholesale distribution activity. A proper quality system should be fully documented, and the effectiveness of the system should be continually monitored to ensure the quality is maintained. This includes ensuring that facilities and equipment are properly maintained for their purposes of storing and distributing prescription drugs; that personnel are properly qualified, screened, and trained for their positions; and that documentation is comprehensive. Regular management review of all aspects of the quality systems in place is important for maintaining these high standards. FDA proposes § 205.26, which establishes basic requirements that will assist wholesale distributors in achieving these goals.

Although the FD&C Act permits an entity to be more than one type of trading partner so long as it complies with all the applicable requirements (section 582(a)(1) of the FD&C Act), FDA believes that the processes and functions of each type of entity need to be kept separate for the licensing authority to ensure the entity is complying with all the applicable requirements. Accordingly, FDA is proposing that any wholesale distributor's facility that is also licensed or registered as another trading partner and operating from the same address must have separate systems and processes in place for their separate functions (see proposed § 205.26(a)).

FDA believes that proper storage and handling of prescription drugs inherently requires the establishment of standards that address physical requirements for the facility space in which drugs are stored and handled, along with standards that address the manner in which drugs are to be securely stored and handled within the facility of a wholesale distributor. In § 205.26(b), FDA proposes the following requirements with regard to standards placed on the wholesale distributor's facility. FDA believes these facility requirements will ensure that their establishments are appropriate for the distribution (including storage) of prescription drugs.

The facility must be of a suitable size, configuration, and design to ensure proper storage, maintenance, and cleanliness (see proposed § 205.26(b)(1)(ii) through (iv)). The facility must also be equipped with clearly defined areas that separate drugs that are unfit for distribution, from those that are saleable to avoid potential mistakes when distributing the prescription drugs (see proposed § 205.26(b)(1)(vi)).

The facility must be sufficiently secure to protect the prescription drugs in the supply chain from possible theft or diversion (see proposed § 205.26(b)(2)). Facilities must protect against unauthorized entry and ensure that the premises are well lit and not vulnerable to intrusion (see proposed § 205.26(b)(2)(i) through (iii)). Entry and access to areas where prescription drugs are held within the facility must be limited to those who have the appropriate experience and training needed to conduct wholesale distribution (see proposed § 205.26(b)(2)(iv)). These basic security requirements will help wholesale distributors protect and safeguard the prescription drugs maintained in their facility.

A wholesale distributor has the responsibility of ensuring that prescription drugs are stored under proper conditions to maintain the safety and effectiveness of the drugs it distributes. Accordingly, a wholesale distributor's facility must maintain appropriate equipment (*e.g.,* refrigeration and air conditioning equipment) in good working order to ensure that prescription drugs are properly stored in the facility (see proposed § 205.26(b)(3)). To this end, FDA is proposing to require that a wholesale distributor establish written procedures to ensure that its equipment is installed and maintained by qualified individuals (see proposed § 205.26(b)(3)(i)). Written policies and procedures include those that are stored and maintained electronically. Upon inspection, a wholesale distributor must demonstrate and verify that its equipment is in working order and has been periodically assessed in accordance with the wholesale distributor's written procedures to ensure the equipment's continued functionality (see proposed § 205.26(b)(3)(i)), which is critical in ensuring that those drugs retain their safety and effectiveness throughout the supply chain.

Additionally, a wholesale distributor must regularly conduct and document facility assessments to make sure that drugs are properly stored in accordance

with their labeling (see proposed § 205.26(b)(4)).

FDA expects that, as a crucial part of the creation of a quality system, wholesale distributors will establish, maintain, and follow written policies and procedures regarding the safeguarding of the prescription drugs within their control. Proposed § 205.26(c) outlines several requirements for maintaining written policies and procedures to ensure that the requirements are carried out properly and consistently. Wholesale distributors are not limited to establishing written policies and procedures for the stated functions in proposed § 205.26(c), as a wholesale distributor may wish to establish written policies and procedures pertaining to other aspects of wholesale distribution and staffing of their facilities. The purpose of requiring written policies and procedures is to assist staff and management at a wholesale distribution facility to determine the processes required to ensure safe storage and distribution of prescription drugs.

Proposed § 205.26(c) includes the requirement that wholesale distributors establish and follow written policies and procedures to ensure that a wholesale distributor: (1) Only does business with other authorized trading partners (see proposed § 205.26(c)(1)); (2) properly maintains equipment in good working order as outlined in proposed § 205.26(b)(3) (see proposed § 205.26(c)(2)); (3) transports prescription drugs in a manner designed to avoid breakage and exposure (see proposed § 205.26(c)(3)); (4) inspects shipping containers for suspect or illegitimate products, as well as other quality issues that may render the prescription drug unfit for distribution (see proposed § 205.26(c)(4)); (5) stores and handles the prescription drugs they warehouse and distribute in accordance with the prescription drug's labeling (see proposed § 205.26(c)(5)); (6) properly retains, returns, or destroys drugs removed from the supply chain depending on the proper disposition of the prescription drug (see proposed § 205.26(c)(6)); and (7) is prepared to protect against reasonably foreseeable crises that could affect security or operations at the facility (see proposed § 205.26(c)(7)).

8. Recordkeeping

Proper recordkeeping is essential to the timely identification, recording, and reporting of issues arising within the supply chain. Section 583(b)(2) of the FD&C Act requires FDA to create national standards for establishing and maintaining records pertaining to the distribution of prescription drugs. FDA is proposing in § 205.27(a) that these records include documentation pertaining to the security, storage, handling, inventory, shipping, sale, purchase, trade, delivery, and receipt of prescription drugs, as well as policies, procedures, instructions, contracts, data, inspection reports, and any other documentation related to compliance with this part, such as invoices, purchase orders, packing slips, and shipping records. These records could be stored and maintained electronically. These records maintenance requirements will allow for greater confidence in the information preserved at the facility and potentially disseminated to other trading partners.

The maintenance, availability, and accuracy of the records made available for inspection under section 583(b)(6) of the FD&C Act are critical to ensure that wholesale distributors are acting in compliance with this proposed regulation and that the records can be relied upon to identify any potential risk to the public health. As such, FDA is proposing to require that all records be securely stored, and that any alterations made to records be signed and dated, while preserving the original information contained in the record (see proposed § 205.27(b)). This is intended to ensure that all records related to the distribution of prescription drugs provide transparency and accurately reflect the activities of the wholesale distributor. FDA also believes that reliability of the records is contingent on having processes and procedures in place that restrict access to and protect the integrity of the data. To this end, FDA is proposing to require in § 205.27(c) that wholesale distributors implement written policies and procedures to protect the integrity of their records.

Under proposed § 205.27(d), all records would be retained for a period of 3 years, except records related to suspect and illegitimate products, prescription drug quality complaints, and destroyed, returned, and recalled prescription drugs, which would need to be retained for a period of 6 years. Such record retention is necessary to ensure compliance and consistent enforcement of the various record keeping requirements of sections 582, 583, and 584 of the FD&C Act.

9. Inspections

Section 583(b)(6) of the FD&C Act directs FDA to establish national standards for a mandatory physical inspection of any facility used in wholesale distribution within a reasonable time frame from the initial application (section 583(b)(6) of the FD&C Act). FDA believes that it is imperative for the mandatory physical inspection to take place prior to issuing an initial license to a wholesale distributor to ensure that only those wholesale distributors who have the ability to properly store, handle, and distribute prescription drugs in accordance with the national standards are licensed. Accordingly, in proposed § 205.28(a), wholesale distributors are required to undergo a physical inspection before the licensing authority issues the initial license. As used in subpart C, *licensing authority* means the State licensing authority or FDA. To satisfy the inspection requirement, section 583(c) of the FD&C Act permits the licensing authority to conduct the inspection or accept an inspection by the State in which the facility is located or by a third-party accreditation or inspection service approved by the licensing authority in accordance with these standards. FDA has codified this provision at proposed § 205.28(a)(1) and (2). Additionally, FDA believes that section 583(c) can be applied to State licensure of non-resident wholesale distributors to ship into a State and proposes that a State into which a drug is distributed may use the same methods to satisfy the inspection requirement for non-resident wholesale distributors (see proposed § 205.28(a)(1)(iii)). FDA believes that requiring a satisfactory inspection prior to licensure will ensure that only wholesale distributors with appropriate facilities and equipment for storing and distributing prescription drugs are granted a license to participate in the supply chain.

FDA is proposing to require that the physical inspection of wholesale distributor facilities include the facility itself, processes related to all wholesale distribution activities, and paper and electronically stored records; that wholesale distributors permit inspections at reasonable times; and that the licensing authority conduct its inspection in a reasonable manner (see proposed § 205.28(b) and (c)). FDA believes that authentication of records during an inspection is important to maintain confidence in documentation preserved by the wholesale distributor, which may contain information about nonsaleable prescription drugs or be disseminated to other trading partners.

FDA proposes that a wholesale distributor be required to make records available during inspections, including records that are held offsite in the normal course of business. The failure of a wholesale distributor to produce

records in a timely manner during an inspection can significantly affect the licensing authority's ability to complete the inspection. Therefore, FDA is proposing that a wholesale distributor be required to provide offsite records within 2 business days of a request for such records by a State or Federal official, or sooner if necessitated by the duration of the inspection (see proposed § 205.28(b)). FDA also proposes the requirement that a wholesale distributor cooperate with the State or Federal licensing authority, or the AO conducting the inspection, at reasonable times, within reasonable limits, and in a reasonable manner to achieve the objective of the inspection (see proposed § 205.28(c)).

Finally, FDA believes routine inspections are an essential tool to ensure that wholesale distributors continue to comply with the national standards after obtaining their initial wholesale distributor license and move to renew that license. Accordingly, FDA is proposing to require that wholesale distributors undergo routine inspections at least once every 3 years (see proposed § 205.28(d)). In developing the inspection timeframes, FDA sought to balance the risk to the supply chain with FDA's and State licensing authorities' resource constraints. These routine inspections allow FDA or the licensing authority to ensure that wholesale distributors maintain the levels of quality storage and maintenance of prescription drugs at their facilities expected by FDA to safeguard the supply chain.

10. Annual and Other Reporting to FDA

Under DSCSA, wholesale distributors must report certain information to FDA as part of the requirement to be considered an authorized trading partner (sections 581(2)(B) and 503(e)(2)(A) of the FD&C Act). The annual reporting requirements for wholesale distributors went into effect on January 1, 2015, and FDA has published draft industry guidance that communicates draft Agency expectations for annual reporting while these regulations are being developed (79 FR 73083, December 9, 2014, and 82 FR 3004, January 10, 2017). Proposed § 205.29 clarifies the statutorily prescribed annual reporting requirements.

The DSCSA requires that any wholesale distributor who owns or operates an establishment that engages in wholesale distribution report to FDA on an annual basis: (1) The State in which the wholesale distributor is licensed; (2) the identification number of its wholesale distributor's license; (3) the name, address, and contact information for the wholesale distributor; (4) all trade names under which the licensed wholesale distributor conducts business; and (5) any significant disciplinary actions taken against the wholesale distributor (section 503(e)(2)(A) of the FD&C Act).

FDA is proposing to require that wholesale distributors use an electronic reporting system provided by FDA (see proposed § 205.29(a)). This electronic system will increase efficiency by providing uniformity in report content and format, making the information easier to process for regularly updating the public database (section 503(e)(2)(B) of the FD&C Act). In addition, FDA believes having the license status of wholesale distributors in one publicly available database would be helpful for FDA, trading partners, and other stakeholders in determining whether wholesale distributors are authorized, as defined in section 581(2)(B) of the FD&C Act. Reporting information for each wholesale distributor in FDA's electronic system during the reporting period is integral to FDA's ability to provide oversight, as wholesale distributors are prohibited from distributing product without a license.

FDA proposes that the annual reporting schedule will require all wholesale distributors to report each calendar year between January 1st and March 31st, although an entity may update information at any time (see proposed § 205.29(b)). For example, if a wholesale distributor chooses to update a license on December 15, 2019, that wholesale distributor will still have to report during the January 1, 2020, through March 31, 2020, annual reporting period.

The specific information that wholesale distributors must electronically report to FDA is set forth in proposed § 205.29(c). The DSCSA requires licensed entities to report to FDA each State by which they are licensed and each license number (section 503(e)(2)(A)(i)(I) of the FD&C Act). FDA is proposing that the wholesale distributor also submit the expiration date of its State licenses (see proposed § 205.29(c)). The submission of the wholesale distributor's license expiration date is paramount to FDA's ability to establish and maintain a public database identifying each authorized wholesale distributor as required by section 503(e)(2)(B) of the FD&C Act. If a wholesale distributor's license expires, it is no longer an authorized trading partner, and FDA will remove it from the public database until the license is renewed or a new license issued. Similarly, FDA is proposing that a wholesale distributor be required to report to FDA within 30 calendar days that it has gone out of business or voluntarily withdrawn a wholesale distributor's license from a State (see proposed § 205.30(e)). Again, FDA believes that requiring a wholesale distributor to report this information about the status of its license is essential for FDA to comply with the requirements under section 503(e)(2)(B) of the FD&C Act and to ensure that the database is accurate and helpful for the States and trading partners.

The DSCSA also requires that wholesale distributors report the name, address, and contact information for each facility at which, and all the trade names under which, the wholesale distributor conducts business (section 503(e)(2)(A)(i)(II) of the FD&C Act). In implementing this requirement, FDA is proposing to require the wholesale distributor to provide the company name that is identical to the official company name appearing on the license, along with the full business address that is associated with the State or Federal license (see proposed § 205.29(c)(2)).

Additionally, FDA is requesting that wholesale distributors submit a UFI that corresponds with the facility name and facility address. The UFI for a wholesale distributor's facility is useful to FDA in identifying and confirming certain business information. A wholesale distributor should obtain a separate UFI for each physical address it reports. FDA has published guidance on annual reporting that can assist wholesale distributors if they require additional information regarding the UFI reporting recommendation.

In addition, FDA believes the wholesale distributor's contact information should include someone familiar with the daily operations of the wholesale distributor's facility and who has the authority to act on inquiries to ensure efficient processing of inquiries and minimize the impact inquiries may have on the facility's daily operations. Therefore, wholesale distributors must submit the contact information of the facility manager or designated representative, including that individual's name, telephone number, and email address, with its annual reporting requirements pursuant to section 503(e)(2)(A)(i)(II) of the FD&C Act.

DSCSA requires a wholesale distributor to report to FDA any significant disciplinary action taken by a State or Federal government against the wholesale distributor (section 503(e)(2) of FD&C Act). A *significant disciplinary action* is defined in the

proposed regulation, in relevant part, as any action by a State or Federal licensing authority that limits or prevents a wholesale distributor from distributing or facilitating the distribution of prescription drugs (see proposed § 205.3(l)). FDA proposes that wholesale distributors report during the reporting period to FDA all significant disciplinary actions that occurred during the preceding 12-month period (see proposed § 205.29(d)(1)). After the reporting period, FDA proposes that within 30 calendar days after a significant disciplinary action is imposed or taken by a State or Federal government, wholesale distributors report the type of disciplinary action, the date the action was taken, and the State where the disciplinary action occurred, as well as submit any documents associated with the disciplinary action, including a final ruling by the relevant State or Federal agency or board or a consent decree (see proposed § 205.29(c)(4) and (d)). While wholesale distributors do not ordinarily have to report DEA registration numbers or State controlled substances licenses to FDA for annual reporting purposes, FDA suggests that such information be provided as part of its report under section 503(e)(2)(A)(ii) of the FD&C Act when there is a significant disciplinary action issued by the DEA or the State controlled substances licensing authority that would limit the ability of the wholesale distributor to distribute controlled drug substances. In such a situation, information about the DEA registration or State controlled substance license should be reported since the disciplinary action is reported under that specific license or registration.

11. Licensure Denial, Suspension, Reinstatement and Revocation—Notice and Opportunity To Request a Hearing

The standards for licensure denial are set forth in proposed § 205.30. Proposed § 205.30(a)(1) lists 10 circumstances under which a licensing authority will be required to deny a wholesale distributor's request for licensure or licensure renewal. FDA believes that these reasons requiring denial will ensure wholesale distributors focus on good storage practices outlined by FDA and are necessary to protect the integrity of the products in the pharmaceutical distribution supply chain. Wholesale distributors should seek to ensure that these reasons outlined in proposed § 205.30(a)(1) are addressed when the wholesale distributor files for licensure to avoid denial or delays of their application.

Proposed § 205.30(a)(2) through (5) details the process afforded to wholesale distributors whose applications for licensure have been denied. FDA is proposing to give applicants the opportunity to provide additional information for reconsideration of the denial. If the licensing authority denies a wholesale distributor's request for licensure after reconsideration, the wholesale distributor will receive a notice of opportunity to request for hearing under existing FDA hearing procedure. FDA requests comment regarding the reconsideration and appeal process outlined in this regulation for wholesale distributors whose applications for licensure have been denied.

The proposed standards for suspending a wholesale distributor's license are set forth in § 205.30(b) and (c). A suspended wholesale distributor must cease all receipt and distribution of prescription drugs until their license is re-instated. The proposed standards for suspension are based on the severity of risk posed to the public health. For example, under proposed § 205.30(b), a wholesale distributor's license may be suspended only after the wholesale distributor receives a notice of opportunity for hearing. If the licensing authority has a reasonable belief that the wholesale distributor is not in compliance with licensure requirements and such noncompliance threatens the quality of the product or threatens public safety, the licensing authority is required to notify the wholesale distributor in writing of the intent to suspend its license. A wholesale distributor will have 30 days upon the date of the notice of intent to suspend a license to provide additional information to the licensing authority so it may reconsider its decision to suspend the wholesale distributor license. If reconsideration is not sought, or if reconsideration is denied, the licensing authority will inform the wholesale distributor in writing of its formal intent to proceed with license suspension. The notice will contain a statement informing the wholesale distributor that it has an opportunity to request a hearing on the question of whether there are sufficient grounds for suspension. The wholesale distributor will have 10 days after the date of the notice to inform the licensing authority of its intent to request a hearing; otherwise the opportunity for a hearing will be waived and the license suspended. FDA requests comment regarding this reconsideration and appeal process.

Proposed § 205.30(c) allows for suspension prior to notice and opportunity for a hearing and for suspension to be effective immediately if the wholesale distributor's noncompliance poses an imminent threat to public safety. For example, if a wholesale distributor is distributing illegitimate product, and once made aware, does not take corrective actions to protect the public from the threat of these products, its license could be suspended immediately. Another example would be a scenario where the conditions under which drugs are held cause the product to be illegitimate and the wholesale distributor refuses to correct the conditions or continues to ship these illegitimate products. Under the proposed regulation, if the licensing authority proceeds with suspension in such a situation, the licensing authority will inform the wholesale distributor in writing that its license is suspended. The notice will also contain a statement informing the wholesale distributor that it may request a hearing and that hearing, if granted, will be afforded within 10 days of the receipt of the wholesale distributor's request for hearing. The wholesale distributor has 10 days from the date on the notice of suspension to request a hearing; otherwise its opportunity for a hearing will be waived. FDA believes that this limits the amount of time a wholesale distributor's license would be suspended while providing a reasonable amount of time both for the wholesale distributor to review a notice of suspension and collect the necessary information to demonstrate that its license should not be suspended, and for FDA to consider the hearing request, and to schedule and prepare for a hearing, if the hearing request is granted. FDA believes immediate suspension of a wholesale distributor's license is crucial in cases where continued operation of the wholesale distributor presents an imminent threat to public safety and the pharmaceutical supply chain.

Under proposed § 205.30(d), a wholesale distributor's suspended license may be reinstated if the wholesale distributor can demonstrate to the licensing authority that it is in compliance with this proposed regulation.

Under the proposed rule the process outlined at § 10.75 is the default for appeals related to a denied application for a wholesale distributor license, and the hearing process outlined at 21 CFR part 16 is the default for appeals related to a suspended or revoked wholesale distributor license. However, the wholesale distributor may request any of the procedures contained in 21 CFR parts 10 through 16. FDA believes that

this proposed approach is consistent with current practice and suggests that States develop comparable processes.

The standards for revoking a wholesale distributor license are set forth in proposed § 205.30(e). The licensing authority will revoke a license if it finds that a wholesale distributor whose license has been suspended is unable or refuses to comply with the licensing requirements. The requirements governing the revocation of a wholesale distributor license are set forth in proposed § 205.30(e)(2) through (4) and mirror the process outlined in § 205.30(b)(2) through (7), with one exception: When the licensing authority informs the wholesale distributor of its intent to revoke a license, the wholesale distributor is given no opportunity for reconsideration since it already had an opportunity to rectify deficiencies while its license was suspended.

In addition, where a wholesale distributor fails to timely renew its application, the license will be considered expired and the wholesale distributor will need to submit an application for new licensure if it seeks to resume wholesale distribution activities, because the licensing authority may be unable to confirm that the wholesale distributor continues to meet all necessary licensure requirements (see proposed § 205.30(f)). If a wholesale distributor's license expires, it must cease receipt and distribution of prescription drugs until their license has been re-instated.

FDA is also proposing that the licensing authority will terminate a wholesale distributor's license upon request from the wholesale distributor when the request includes a notice of the wholesale distributor's intent to discontinue its activities and a waiver of an opportunity for a hearing. The wholesale distributor will be required to apply for a new license should it decide to resume wholesale distribution activities (see proposed § 205.30(g)).

F. Approved Organizations for Wholesale Distributors

1. Approval of Outside Organizations and Utilization of Such Organizations in the Licensure Process

The FD&C Act, as amended by DSCSA, allows the Federal or State licensing authority to accept inspections of wholesale distributors conducted by third-party accreditation or inspection services they have approved to be part of the licensure process (section 583(c) of FD&C Act). Subpart D of the proposed rules defines the scope of work these approved organizations (AOs) would be tasked with performing, as well as the standards an AO must meet to become approved by FDA. Additionally, this subpart will explain the circumstances in which an inspection conducted by an AO may be used, what activities the AOs have the authority to conduct and are expected to conduct, and the qualifications that each third-party organization must possess to become approved by FDA. FDA suggests that States that choose to rely on AOs to conduct inspections have in place the same or similar qualifications and processes for approved organizations to conduct those inspections and for decisions affecting the approval status of those organizations.

FDA proposes that an AO must complete an inspection no more than 90 days after receiving notice from the licensing authority to conduct an inspection (see proposed § 205.31(b)). FDA believes this allows AOs sufficient time to perform the work with which they are tasked while also ensuring that the wholesale distributor's activities are not significantly delayed or otherwise impacted due to delays in the inspection process. Upon completion of the inspection, the AO would then provide FDA with a report based on the inspection within 7 days (see proposed § 205.31(b)(2) and (3)), with copy of the report to the wholesale distributor facility (see proposed § 205.31(b)(3)). Using the report submitted by the AO, FDA makes the final determination as to whether a wholesale distributor facility should be issued a license.

It is important that FDA be able to verify an AO's continued compliance with the requirements of the proposed regulation. Therefore, to become an AO and keep its approval, FDA is proposing to require that an AO maintain certain records for a period of at least 5 years and make these records readily available to FDA upon request (see proposed § 205.31(c)). In addition, to ensure public safety, FDA is proposing to require that AOs report certain observations at wholesale distributor facilities to FDA immediately (see proposed § 205.31(c)(4)). The general qualifications for approval are set out in proposed § 205.32.

To become and remain approved, FDA is proposing to require that an organization, and those employed by the organization, abide by certain guidelines intended to secure against conflicts of interest, promote professional business practices, and protect non-public information (see proposed § 205.32(a)).

FDA is proposing to allow AOs to hire outside contractors to conduct inspections. Under FDA's proposed regulation, AOs who decide to use outside contractors must ensure that they effectively carry out the inspection in a manner consistent with this proposed regulation to protect public health, conform to conflict of interest provisions, and properly protect all non-public information (see proposed § 205.32(b)). For an AO to maintain approval, FDA proposes to require that the AO ensure contractors abide by all applicable confidentiality agreements, the AO has policies and procedures in place to ensure the contractors abide by these proposed standards, and the contractors have the necessary training and expertise to carry out inspections of wholesale distributor facilities (see proposed § 205.32(b)(1)).

Before a contractor hired by an AO may perform an inspection of a wholesale distributor, the wholesale distributor must have entered into an agreement with the AO giving the AO permission to share with contractors the wholesale distributor's confidential commercial information (see proposed § 205.32(b)(2)). If such consent is not provided by the wholesale distributor, the AO will perform the inspection itself, without the use of contractors. FDA believes that this approach is reasonable given that it is the AO's decision to work with contractors and, under this proposed regulation, the ultimate responsibility for the inspection and the protection of the wholesale distributor's information rests with the AO.

In addition, FDA proposes that AOs must submit to FDA a list of the contractors used by the organization and must certify that such contractors comply with the applicable regulations (see proposed § 205.32(b)(3)). Finally, to ensure that the standards set forth in this subpart are followed, FDA proposes to require that the AOs remain responsible for all the work performed by outside contractors (see proposed § 205.32(b)).

FDA proposes that to maintain their approved status, AOs must prohibit contractors from subcontracting their inspection duties (see proposed § 205.32(b)(1)(ii)). Limiting the ability of contactors to further delegate their responsibility ensures that FDA will have accurate information about who is conducting inspections, that those responsible for the inspections have the necessary qualifications, and that their conduct is governed by this proposed regulation.

The proposed process that FDA will use to approve organizations, including the application process, as well as the process for suspending or revoking an organization's approval, are set forth in proposed § 205.33. FDA is proposing that organizations seeking approval by

FDA must electronically submit to FDA an application demonstrating the organization's ability to assess compliance with all wholesale distributor requirements detailed in proposed part 205 (see proposed § 205.33(a) and (b)), and employees must complete the necessary training as directed by FDA (see proposed § 205.33(c)). To verify information contained in the application and ensure compliance with the proposed regulation, FDA proposes that, before an AO may conduct its first inspection, a newly approved organization must be audited by FDA (see proposed § 205.33(d)). A new approval will be valid for 5 years (see proposed § 205.33(e)).

If an organization's request for approval is denied, the organization may submit a request for reconsideration under § 10.75 (see proposed § 205.33(f)). In addition, FDA proposes that an AO may have its approval suspended if it does not maintain the standards outlined in this section (see proposed § 205.33(g)). A suspended AO must cease all inspections of wholesale distributors. A suspended AO must notify any wholesale distributors with a pending inspection to be performed by the AO of the AO's suspension within 7 calendar days (see proposed § 205.33(g)(5). While most suspensions will happen only after notice and opportunity to request a hearing, under the proposed regulations, FDA reserves the ability to suspend approval prior to a hearing if there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans (see proposed § 205.33(h)).

Furthermore, FDA proposes that a suspended approval can be reinstated if the issue is resolved within 1 year from the date of suspension (see proposed § 205.33(i)), though it may be revoked if the organization fails to rectify the situation that resulted in the suspension (see proposed § 205.33(j)). FDA believes that 1 year provides the AO enough time to remedy most situations. An AO's approval may also be reinstated on a conditional basis. If the AO is conditionally reinstated, they will enter a three-year probationary period, during which if any material deficiencies arise, their approval will be subject to immediate revocation (see proposed § 205.33(i)(2)).

FDA also proposes to permit an AO to voluntarily withdraw its approval or otherwise cease operations as an AO under this part, but it must inform FDA of any facilities with pending inspections (see proposed § 205.33(l)). To further ensure that pending inspections are not overlooked, under FDA's proposed regulation, an AO whose approval has been suspended or revoked has the responsibility to report this information to those wholesale distributors that have pending inspections (see proposed § 205.33(m)); this will stop the clock on the 90-day licensure review while the wholesale distributor applies for inspection from another AO or FDA. Also, to ensure wholesale distributors continue to comply with the provisions of this part, and to ensure that AOs remain able to assess compliance with the wholesale distributor requirements, an AO must inform FDA of any changes to information that was submitted as part of its application for approval (see proposed § 205.33(n)(1)). Since the approval of an organization is nontransferable, changes in ownership require an AO to submit a new application to FDA (see proposed § 205.33(n)(2)). Finally, as an additional assurance that an AO continues to comply with the provisions of this part, FDA proposes to require that AOs remain subject to periodic audits by FDA (see proposed § 205.33(o)).

VI. Proposed Effective/Compliance Dates

Section 584 of the FD&C Act states that the national licensing standards for 3PLs established by regulation take effect 1 year after the date such final regulation is published (section 584(d)(1) and (3) of the FD&C Act), and that national licensing standards for wholesale distributors established by regulation take effect 2 years after the date such final regulation is published (section 583(a) and (e)(3) of the FD&C Act). For several reasons, FDA does not intend to enforce the 3PL requirements until 2 years after the final regulation is published.

FDA recognizes that 1 year may be insufficient time for States to implement 3PL licensure programs, should they decide to implement such programs, and for 3PLs to apply for licensure under these programs. Setting up a state licensure program may require additional time. This is especially true in States that will require State legislative action to implement a licensure program, with some State legislatures only meeting biennially.

As the DSCSA states that the national standards for prescription drug wholesale distributors established by regulation pursuant to section 583 of the FD&C Act will take effect 2 years after the date such final regulation is published (section 583(a) and (e) of the FD&C Act), the national standards for licensing wholesale distributors in subpart C will be effective 2 years after the date the final rule is published.

Although the DSCSA states that the national licensing standards for 3PLs established by regulation pursuant to section 584 of the FD&C Act will take effect one year after the date such final regulation is published (section 584(d)(1) and (3) of the FD&C Act), as noted, FDA does not intend to enforce requirements with respect to the national standards for licensure of 3PLs until *2* years after the regulation is finalized, in order to provide States with the opportunity to establish or modify their licensure programs in accordance with the new standards and time for 3PLs to apply and obtain a new license. For 1 year after the effective date of the final regulation, FDA also does not intend to enforce the requirements of section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act with respect to a manufacturer, wholesale distributor, dispenser, or repackager who has as a trading partner a 3PL that is not licensed, unless the 3PL is not licensed because the Secretary or a state licensing body has made a finding that the 3PL does not utilize good handling and distribution practices and the Secretary has published notice thereof.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule could impose significant, although uncertain, new economic burdens on small entities, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing

''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

In this rulemaking, we propose new national standards for the licensing of prescription drug wholesale distributors and third-party logistics providers as directed under the Drug Supply Chain Security Act, Title II of the Drug Quality and Security Act. If finalized, the rule would also establish a Federal licensing system for wholesale drug distributors and third-party logistics providers to use in the absence of a state licensure program that is consistent with the proposed national standards.

This rulemaking is being published in conjunction with the proposed rule entitled ''Certain Requirements Regarding Prescription Drug Marketing'' (or part 203), published elsewhere in this issue of the **Federal Register**. We include the benefits and costs of part 203 in this economic analysis and, unless otherwise specified, references to the ''proposed rule'' in this analysis encompass both proposed rules.

We summarize the benefits and costs of the proposed rule in table 1. The standards for prescription drug wholesale distribution in the proposed rule would result in benefits to consumers and benefits to distributors from reducing the diversion of prescription drugs. Other monetized benefits include cost savings from reducing the frequency and quantity of licensure applications and cost savings from reducing state licensing standards in some states. We estimate that the annualized benefits over 10 years would range from $1.25 million to $31.50 million at a 7 percent discount rate, with a primary estimate of $10.66 million. We estimate that the annualized benefits would range from $1.26 million to $32.18 million at a 3 percent discount rate, with a primary estimate of $10.89 million.

We also expect that the proposed rule, if finalized, would impose costs on wholesale drug distributors, third-party logistics providers, states, approved organizations, and the Food and Drug Administration (FDA). Costs to wholesale drug distributors and third-party logistics providers include costs of learning about the rule, reporting to FDA, undergoing routine inspections, writing and revising standard operating procedures, and conducting background checks. Wholesale-drug distributors would also incur costs to furnish surety bonds to their state licensing authority to obtain or renew their licenses.

Costs to states include the time spent reading and understanding the rule, passing or revising the laws and regulations governing their licensure programs, and inspecting WDD and 3PL facilities. Approved organizations would incur legal, application, and training costs, as well as costs to inspect WDD and 3PL facilities. FDA costs include the costs to establish and operate a reporting database and a licensure program for wholesale drug distributors and third-party logistics providers and the costs to establish and operate an approval program for approved organizations.

We estimate that the annualized costs over 10 years would range from $13.21 million to $20.63 million at a 7 percent discount rate, with a primary estimate of $16.92 million. We estimate that the annualized costs over 10 years at a 3 percent discount rate would range from $12.83 million to $20.10 million, with a primary estimate of $16.47 million.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized ($ millions/year)	$10.66	$1.25	$31.50	2020	7	10	There is a high degree of uncertainty in the magnitude of benefits.
	10.89	1.26	32.18	2020	3	10	
Qualitative.							
Costs:							
Annualized Monetized ($ millions/year)	16.92	13.21	20.63	2020	7	10	
	16.47	12.83	20.10	2020	3	10	
Qualitative.							
Transfers:							
Federal Annualized Monetized ($ millions/year)	0.12	0.09	0.14	2020	7	10	
	0.11	0.08	0.14	2020	3	10	
	From: States			To: Firms			
Other Annualized Monetized ($ millions/year)	.....	.....	.....	.....	.....	.....	
	From:			To:			

Effects:
State, Local, or Tribal Government: Annualized net costs to states over 10 years ranging from $0.62 million to $1.44 million at a 7 percent discount and from $0.58 million to $1.38 million at a 3 percent discount rate.
Small Business: Quantified effects of more than 1 percent of average annual revenues for small 3PL firms. Unquantified effects are uncertain.
Wages: No estimated effect.
Growth: No estimated effect.

We have developed a comprehensive Preliminary Economic Analysis of Impacts (PRIA) that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref 18) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VIII. Analysis of Environmental Impacts

FDA has carefully considered the potential environmental effects of this action and has concluded, under 21 CFR 25.30(h), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the Description section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Requirements to Obtain a License to Distribute Drugs, Annual Reporting and Recordkeeping for Procedures, for Third-Party Logistics Providers and Prescription Drug Wholesale Distributors to Obtain a License to Distribute Drugs; 21 CFR part 205; OMB Control Number 0910–0251—Reinstatement

Description: The proposed rule would establish standards, terms, and conditions for the licensing of 3PLs and prescription drug wholesale distributors by State or Federal licensing authorities, including process for the revocation, reissuance, and renewal of such licenses. Sections 584 and 583 of the FD&C Act (21 U.S.C. 360eee–3, 360eee–2)) as added by the DSCSA (Title II of Pub. L. 113–54) requires FDA to issue regulations on national standards for the licensing of 3PLs and wholesale distributors. Accordingly, FDA is proposing requirements for licensing of wholesale distributors and third-party logistics providers. The proposed rule outlines these requirements, including information collection provisions, that 3PLs and wholesale distributors must meet to obtain a license. The licensing authority is the State, from which the 3PLs distribute drug or the State from which wholesale distributors distribute drug. However, if a State does not establish the licensure programs for 3PLs or wholesale distributors consistent with these regulations, FDA will issue the licenses to 3PLs or wholesale distributors in that State. In addition, States may require that a 3PL or a wholesale distributor obtain a license to ship drugs into that State. The FD&C Act does not require that States issue these types of licenses. However, if a State chooses to implement such a licensure requirement, the State must ensure that it is consistent with these regulations, and any wholesale distributor or 3PL wishing to ship products into that State must have a license.

Proposed part 205, subpart A, would set forth the national licensing standards for State and Federal licenses issued to 3PLs pursuant to section 584 of the FD&C Act (21 U.S.C. 360eee–3). Proposed part 205, subpart C, would set forth the national licensing standards for State and Federal licenses issued to wholesale distributors pursuant to sections 503(e) and 583 of the FD&C Act (21 U.S.C. 353(e) and 21 U.S.C. 360eee–2)) and replaces the existing regulations in proposed part 205 that outlined guidelines for State licensing of wholesale distributors that were developed under the Prescription Drug Marketing Act of 1987 (Pub. L. 100–293).

In addition, the FD&C Act, as amended by DSCSA, allows FDA to approve ''third party accreditation'' entities to evaluate the qualifications of 3PLs for licensure or inspect wholesale distributors facilities on behalf of FDA. These organizations are referred to in this proposed rule as approved organizations or ''AOs.'' The application to become an AO is the same whether the AO will be evaluating the qualifications of 3PLs for licensure, inspecting wholesale distributors facilities, or both. Subparts B and D of the proposed rule outline the qualifications for AOs to perform licensure reviews/inspections for 3PL facilities and inspections of wholesale distributors respectively.

Description of Respondents: Respondents to the information collection are third-party logistics providers and wholesale distributors in any State and any entity engaging in wholesale distribution of prescription drugs in any State. We are proposing that these respondents submit applications for licensure and maintain records of procedures and documents pertaining to licensure review, inspections, policies, and training.

The DSCSA establishes 3PLs as members of the drug supply chain, which are distinct from wholesale drug distributors, and specifically precludes States from regulating 3PLs as wholesale distributors (section 585(b)(2) of the FD&C Act (21 U.S.C. 360eee–4(b)(2)). FDA is required by section 584 of the FD&C Act (21 U.S.C. 360eee–3) to establish national standards for the licensure of 3PLs and is proposing those standards in part 205, subpart A. When the proposed rule is finalized, we will require that each facility of an entity that meets the definition of a 3PL in section 581(22) of the FD&C Act (21 U.S.C. 360eee(22)) be licensed by the State or FDA in accordance with the standards articulated in proposed part 205, subpart A.

Proposed part 205, subpart C, of the proposed rule, §§ 205.20 through 205.30, establishes the national standards for the licensure of wholesale drug distributors. When the proposed rule is finalized, we will require that each wholesale distributor be licensed by the State or FDA in accordance with the standards in proposed part 205, subpart C.

Proposed part 205, subpart B (§§ 205.17 through 205.19), and subpart D (§§ 205.31 through 205.33), of the proposed rule describe the content requirements, application process, and reporting schedules to become an approved organization to conduct licensure review/inspections for 3PL facilities or conduct inspections of wholesale distributors. Although the work differs among licensure review and inspection for 3PLs and wholesale distributors, FDA believes that the same entities will apply to conduct licensure reviews and inspection of both types of entities. In addition, the submission of an application to become an AO is the same in subparts B and D. Because of this, we are combining the discussions of AOs for 3PLs and wholesale distributors, and the resulting burden estimates.

The national licensure standards FDA is proposing are intended to help ensure that the supply chain remains secure and that those finished prescription drug products subject to the DSCSA moving through the supply chain are properly stored, handled, and transported. These measures are

intended to help protect U.S. consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The required information collection to comply with the proposed rule is necessary for the States or FDA to assess the ability of 3PLs or wholesale distributors to properly maintain drug quality and security while the drug products are under their possession or control.

We estimate the burden of the information collection as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Proposed 21 CFR part 205 section; IC activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Subpart A (3PLs):					
§§ 205.5 and 205.6; application and process requirements	459	1	459	2	918
§ 205.7; changes to licensure	6	1	6	1	6
§ 205.8; expiry and renewal of licensure	149	1	149	1	149
§ 205.9; denials, suspensions, reinstatements, revocations	35	1	35	1	35
§ 205.11; personnel list	459	1	459	.5	230
§ 205.15; annual reports	459	1	459	.25	115
Subpart B (Approved Organizations for 3PLs):					
§ 205.17; licensure review and inspection reports of 3PL facilities	6	15	90	5	450
§ 205.19; applications, denials, revocations, suspensions, renewals, reinstatements for AO status	3	1	3	2	6
Subpart C (WDD Standards):					
§§ 205.22 and 205.23; application and process requirements for licensure	1,951	1	1,951	2	3,902
§ 205.24; changes to WDD information	39	1	39	1	39
§ 205.26; confirmation of theft or loss of Rx drug	25	1	25	.5	13
§§ 205.29 and 205.30; denials, suspensions, reinstatements, revisions, and terminations—requests for hearing	38	1	38	1	38
§ 205.29(a)—WDD annual reports	1,951	1	1,951	1	1,951
Subpart D (Approved Organizations for WDDs):					
§§ 205.32 and 205.33; documentation of qualifications and disclosures to FDA	6	31	186	5	930
Total			5,890		

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Proposed 21 CFR part 205 section; IC activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Subpart A (3PLs):					
205.4; general requirements (retrievable records)	459	1	459	.5	230
205.12; written procedures	459	1	459	21	9,639
205.13; record and document maintenance	459	1	459	1	459
205.14; list of trading partners	459	1	459	2	918
Subpart B (Approved Organizations for 3PLs):					
205.17; licensure review and inspection records	6	15	90	2	180
205.19; written procedures, policies, training records	6	1	6	3	18
Subpart C (WDD Standards):					
205.21; surety bond	1,951	1	1,951	1	1,951
205.25; personnel records	1,951	1	1,951	1	1,951
205.26; facility records	1,951	1	1,951	1	1,951
205.28; inspection records	1,951	1	1,951	1	1,951
Subpart D (Approved Organizations for WDDs):					
205.31; records demonstrating qualification status	6	1	6	1	6
Total			9,742		19,254

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

Reporting Burden

Among the reporting requirements found in proposed part 205 are content and format provisions pertaining to issuance, changes, expiry, renewal, and annual reports for 3PLs, as well as WDDs, as reflected above in table 3. The proposed regulations also prescribe procedural steps and reporting schedules for submitting information regarding licensure, changes to

licensure, reinstatement, and annual reporting, including requisite reporting timeframes. Consistent with our PRIA, we estimate that 459 3PL facilities and 1,951 WDDs will become subject to the reporting requirements described in proposed part 205, where we ascribe specific burden associated with the provisions found in table 3. Because we currently lack specific submission data regarding the proposed reporting requirements, we rely on our experience with similar information collection as the primary basis for our estimates. However, we invite specific comment from potential respondents regarding burden estimates we ascribe to the reporting elements found in the proposed regulations, along with a discussion of the basis for their computation.

Recordkeeping Burden

As set forth in the proposed regulations, 3PLs and WDDs must maintain records documenting procedures, management practice, policies, training, and personnel, among others. Under proposed § 205.4, all records are subject to FDA inspection and must be made available upon request in the format prescribed by the proposed regulations. Additional specific recordkeeping practice elements are also enumerated in the proposed regulations. Consistent with our PRIA, we estimate that 459 3PLs and 1,951 WDDs will become subject to these requirements, if the proposed rule is finalized. These provisions are reflected above in table 4, along with an estimated number of annual records and recordkeeping hours we attribute to the corresponding activity. As with the proposed reporting requirements, we currently lack specific data regarding recordkeeping associated with the proposed regulations. We invite specific comment from potential respondents regarding burden estimates we ascribe to the recordkeeping activities, along with a discussion of the basis for their computation.

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through *reginfo.gov* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132, ''Federalism'' (64 FR 43255, August 10, 1999). This Executive order sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, defined in section 1(a) of the order as including regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Section 4(a) of the Executive order requires agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' The DSCSA added to the FD&C Act an express preemption provision under section 585, which addresses state licensure of WDDs and 3PLs in section 585(b)(1).

A. Scope of Preemption

FDA interprets section 585(b)(1) of the FD&C Act as preempting States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the standards and requirements applicable under sections 584 and amended 503(e) of the FD&C Act. In other words, States and local governments may not establish or continue licensure requirements for 3PLs or WDDs unless those State requirements are the same as Federal requirements; different requirements are preempted.

As noted above, a draft guidance issued in October 2014 (Ref. 4) proposed a different preemption interpretation under which States and localities could impose requirements on 3PL and WDD licensure that were different from Federal requirements so long as those requirements did not fall below the minimum Federal standards. Several stakeholders commented that the agency's interpretation of section 585(b)(1) was too narrow. Instead, they argued Congress intended to preempt all state licensure laws not identical to Federal licensure standards, *i.e.,* that Congress wanted the Federal system to provide both a ''floor'' and a ''ceiling'' when it came to the issue of preemption.

FDA has reconsidered its earlier proposed interpretation and determined that its current interpretation—that the Federal requirements will establish both a ''floor'' and a ''ceiling''—is more consistent with the language of the statute, Congressional purpose, and policy considerations. Section 585(b)(1) provides for the preemption of any state requirements that are, among other things, ''inconsistent with'' or ''covered by'' Federal requirements—which suggests both a floor and a ceiling. Furthermore, the fundamental purpose of the DSCSA provisions was to strengthen the security and integrity of the drug supply chain through uniform national requirements (Refs 2, 3, 18), including with respect to licensure (see *e.g.,* section 583(b)). In contrast, under the interpretation proposed in our October 2014 draft guidance, 3PLs and WDDs could be required to comply with a patchwork of State and local licensure requirements, which would undermine the goal of national uniformity and could create barriers to the statute's implementation and administrability. That approach would not create the intended uniformity in national policy because States and localities would not be preempted from establishing unique or disparate requirements.

Accordingly, FDA is withdrawing, as of the date of publication of this proposed rule, that portion of the October 2014 draft guidance addressing preemption with respect to WDD/3PL licensure.

B. Effective Date of Preemption

Section 585(b)(1) provides that it is effective ''[b]eginning on the date of enactment of the Drug Supply Chain Security Act [November 27, 2013].'' However, that provision applies only to state requirements that are inconsistent with the national standards and requirements applicable under sections 584 and 503(e) of the FD&C Act. Those national standards will be established by this regulation, once finalized and effective. Thus, by its very terms, section 585(b)(1) has no current application. Accordingly, State and local licensure requirements will be preempted only once this regulation, when finalized, takes effect; until such time, current State and local licensing of WDDs and 3PLs may continue.

We believe that this result is dictated by the terms of the statute. However, even if the statute were considered ambiguous, this interpretation is consistent with the statutory framework and purposes. Other provisions added

by the DSCSA recognized state licensure of WDDs and 3PLs before the effective date of this regulation. For example, DSCSA requires both WDDs and 3PLs to report their state licensure, beginning January 1, 2015, for WDDs and November 27, 2014, for 3PLs (see sections 503(e)(2)(A) and section 584(b)). Because these reporting requirements apply during the period between DSCSA's enactment and the effective date of Federal licensing standards, they suggest that Congress intended to preserve the status quo in terms of permitting state licensure during this interim period. Indeed, if state licensing were viewed as preempted during this interim period, there could be no valid state licensure for 3PLs and WDDs to report, rendering this reporting provision meaningless. In addition, section 582(a)(6) expressly recognizes state WDD licensure during the period between DSCSA's enactment and the effective date of Federal licensure regulations, and section 582(a)(7) similarly deems 3PLs to be ''licensed'' during this time, including by acknowledging and accommodating state licensure of 3PLs.

Further, the WDD licensure rules take effect two years after publication of the final rule, per section 583(e)(3), and the 3PL rules take effect one year after publication of the final rule, per section 584(d)(3)(C). Thus, despite the reference to DSCSA's enactment date in section 585(b)(1), the statute also expressly provides that the Federal licensure standards will not be effective until several years after DSCSA's enactment.

The interpretation is also supported by reading the provisions of a statute as an integrated whole, consistent with its fundamental purpose. As noted, the purpose is to strengthen the security and integrity of the drug supply chain through uniform national requirements, including with respect to licensure. This purpose would be frustrated if the statute were implemented in a manner that could lead to supply chain disruption, due to licensing uncertainties, while the national licensure standards are pending. Thus, Congress included in the DSCSA provisions which recognize state licensure of WDDs and 3PLs prior to the effective date of Federal licensing standards. If preemption under section 585(b)(1) were construed to preempt states from continuing to license WDDs and 3PLs even before Federal standards are in place, there could be confusion whether these supply chain entities have valid licensure, to the detriment of supply chain operations. Accordingly, we believe that read as a whole, the statute can be reasonably interpreted as providing for preemption to apply only upon the effective date of this regulation, once finalized.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. 159 Cong. Rec. S8028 (2013) (Statement of Senator Barbara Mikulski); available at: *https://www.congress.gov/113/crec/2013/11/14/CREC-2013-11-14-pt1-PgS8027-6.pdf.*

* 2. 159 Cong. Rec. H5964 (2013) (Statement of Representative James Matheson); available at: *https://www.congress.gov/113/crec/2013/09/28/CREC-2013-09-28-pt1-PgH5946-2.pdf.*

* 3. 159 Cong. Rec. H5962 (2013) (Statement of Representative Robert Latta); available at: *https://www.congress.gov/113/crec/2013/09/28/CREC-2013-09-28-pt1-PgH5946-2.pdf.*

* 4. FDA, Guidance for Industry: ''Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers'' October 2014, (available at *https://www.fda.gov/media/89954/download*), accessed December 14, 2021.

* 5. Ducca, A., Healthcare Distribution Management Association, Public comment letter Document ID: FDA–2014–D–1411–0012, submitted on December 24, 2014, to Docket No. FDA–2014–D–1411 pertaining to the ''Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Availability,'' October 8, 2014 (available at *https://www.regulations.gov/document?D=FDA-2014-D-1411-0012*), accessed December 14, 2021.

* 6. Ventimiglia, V., Pharmaceutical Distribution Security Alliance, Public comment letter Document ID: FDA–2014–D–1411–0007, submitted on December 24, 2014, to Docket No. FDA–2014–D–1411 pertaining to the ''Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Availability,'' October 8, 2014 (available at *https://www.regulations.gov/document?D=FDA-2014-D-1411-0007*), accessed December 14, 2021.

* 7. Rouse O'Neill, L., Health Industry Distributors Alliance, Public comment letter Document ID: FDA–2014–D–1411–0013, submitted on December 24, 2014, to Docket No. FDA–2014–D–1411 pertaining to the ''Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Availability,'' October 8, 2014 (available at *https://www.regulations.gov/document?D=FDA-2014-D-1411-0013*), accessed December 14, 2021.

8. Gallenagh, E.A, L.F. Hirsch, and K.L. Palmer, ''Title II—Licensure of Wholesale Distributors and 3PLs,'' presented at Food and Drug Law Institute's Drug Quality Security Act Conference, November 15, 2017 (available at *https://www.fdli.org/wp-content/uploads/2017/11/DQSA-Hrisch-B.pdf*), accessed December 14, 2021.

9. National Association of Boards of Pharmacy, ''Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply,'' August 2013 (available at *https://nabp.pharmacy/wp-content/uploads/2016/07/wholesale-drug-distribution-protecting-the-integrity-of-the-nations-prescription-drug-supply.pdf*), accessed December 14, 2021.

10. United States Department of Justice, ''Three California Men and Minnesota Corporation Indicted in Nationwide Prescription Drug Diversion Scheme,'' May 2015 (available at *https://www.justice.gov/opa/pr/three-california-men-and-minnesota-corporation-indicted-nationwide-prescription-drug*), accessed December 14, 2021.

* 11. United States Department of Justice, ''Two Plead Guilty In Prescription Drug Diversion Scheme,'' May 2014 (available at *https://www.justice.gov/usao-mdtn/pr/two-plead-guilty-prescription-drug-diversion-scheme*), accessed December 14, 2021.

12. National Association of Boards of Pharmacy, ''Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy'' (available at *https://*

nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/), accessed December 14, 2021.

13. Healthcare Distributors Alliance, ''HDA Model Licensure Standards for Third-Party Logistics Providers for FDA Consideration,'' February 2015 (available at *https://www.hda.org/~/media/pdfs/government-affairs/2015-02-10-traceability-resource-3pl-licensure-model.ashx*), accessed December 14, 2021.

* 14. World Health Organization, ''Annex 5: WHO good distribution practices for pharmaceutical products,'' 2010 (available at *https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf*)), accessed December 14, 2021.

15. National Association of Boards of Pharmacy and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) (available at *https://www.picscheme.org/*), accessed December 14, 2021.

* 16. U.S. Food and Drug Administration, ''Prescription Drug Marketing Act, Report to Congress,'' June 2001 (available at *https://wayback.archive-it.org/7993/20170405002846/https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/ucm203148.htm*), accessed December 14, 2021.

17. National Association of Boards of Pharmacy, ''Prescription Medication Distribution—The Five Percent Rule for Resale (Resolution 109–2–13),'' June 2013 (available at *https://nabp.pharmacy/news/news-releases/prescription-medication-distribution-the-five-percent-rule-for-resale-resolution-109-2-13/*), accessed December 14, 2021.

18. FDA, ''National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers; Preliminary Regulatory Impacts Analysis,'' (available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*).

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Parts 12 and 16

Administrative practice and procedure.

21 CFR Part 205

Intergovernmental relations, Prescription drugs, Reporting and recordkeeping requirements, Security measures, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 10, 12, 16, and 205 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 1. The authority citation for part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

■ 2. In § 10.50, add paragraph (c)(21) to read as follows:

§ 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.

* * * * *

(c) * * *

(21) Sections 503(e), 583, and 584 on denial, suspension, or revocation of third-party logistics provider licenses or wholesale distributor licenses.

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

■ 3. The authority citation for part 12 continues to read as follows:

Authority: 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b–263n, 264; 15 U.S.C. 1451–1461; 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

■ 4. In § 12.21, revise paragraphs (a) introductory text and (a)(2) to read as follows:

§ 12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.

(a) A proceeding under section 503(e); 505(d) or (e); 512(d), (e), (m)(3) or (4); 515(g)(1); 583; or 584 of the Federal Food, Drug, and Cosmetic Act, or section 351(a) of the Public Health Service Act, may be initiated—

* * * * *

(2) By a petition in the form specified elsewhere in this chapter, *e.g.,* § 205.9 for licenses for third-party logistics providers, § 205.30 for licenses for wholesale distributors, § 314.50 for new drug applications, § 514.1 for new animal drug applications, § 514.2 for applications for animal feeds, or § 601.3 for licenses for biologic products; or

* * * * *

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 5. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 6. In § 16.1:

■ a. Designate the 16 undesignated paragraphs immediately following paragraph (b)(1) as paragraphs (b)(1)(i) through (xvi).

■ b. In paragraph (b)(2):

■ i. Remove ''§§ '' and ''§ '' everywhere they appear and add ''Sections'' and ''Section'' in their places, respectively;

■ ii. Designate the first 14 undesignated paragraphs immediately following paragraph (b)(2) as paragraphs (b)(2)(i) through (xiv);

■ iii. Add paragraphs (b)(2)(xv) and (xvi); and

■ iv. Designate the last 23 undesignated paragraphs as paragraphs (b)(2)(xvii) through (xxxix).

The additions read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

(xv) Section 205.19, relating to revocation or suspension of approval for an approved organization to conduct licensure reviews for third-party logistics provider applicants.

(xvi) Section 205.33, relating to revocation or suspension of approval for an approved organization to conduct inspections of wholesale distributors.

* * * * *

■ 7. Revise part 205 to read as follows:

PART 205—NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS AND PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS

Sec.

205.1 Scope.
205.2 Purpose.
205.3 Definitions.

Subpart A—Third-Party Logistics Providers Licensure Standards

205.4 Requirement that third-party logistics providers be licensed.
205.5 General application requirements for licensure.
205.6 Federal licensure process.
205.7 Changes to information, location, or ownership of a licensed 3PL.
205.8 Expiry and renewal.
205.9 Licensure denial, suspension, reinstatement, revocation, and voluntary termination: notice and opportunity to request a hearing.
205.10 Good storage practices for 3PL facilities.
205.11 Personnel requirements necessary for good storage practices.
205.12 Required written policies and procedures.
205.13 Recordkeeping and document maintenance.
205.14 3PLs must provide upon request a list of trading partners.
205.15 Requirements for initial and annual reporting to the Food and Drug Administration.
205.16 Inspections.

Subpart B—Approved Organizations for 3PLS

205.17 Use of approved third-party organizations.

205.18 General qualifications of approved organizations.
205.19 Process and procedures for approval by the Food and Drug Administration.

Subpart C—Wholesale Distributors Licensure Standards

205.20 Requirement that prescription drug wholesale distributors be licensed.
205.21 Surety bond requirement.
205.22 General application requirements for licensure.
205.23 Federal licensure process.
205.24 Changes to information, operation, location, or ownership of a wholesale distributor.
205.25 Prohibited persons and qualifications for key personnel.
205.26 National standards for the storage and handling of prescription drugs for wholesale distribution.
205.27 Standards for the establishment and maintenance of records of the distribution of prescription drugs.
205.28 Inspections.
205.29 Requirements for initial and annual reporting to the Food and Drug Administration.
205.30 Licensure denial, suspension, reinstatement, revocation, and voluntary termination—notice and opportunity to request a hearing.

Subpart D—Approved Organizations for Wholesale Distributors

205.31 Use of approved third-party organizations.
205.32 General qualifications of approved organizations.
205.33 Process and procedures for approval by the Food and Drug Administration.

Authority: 21 U.S.C. 351, 352, 353, 360eee–2, 360eee–3, 360eee–4, 371, 374.

§ 205.1 Scope.

(a) This part applies to the licensure of third-party logistics providers (3PLs) in any State and to any entity engaging in wholesale distribution of prescription drugs in any State. The standards established under subpart A of this part will apply to all State and Federal licenses described under sections 503(e)(5) and 584 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(5) and 360eee–3). The standards established under subpart C of this part will apply to all State and Federal licenses described under sections 503(e)(1) and 583 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(1) and 360eee–2).

(b) A facility or entity that conducts 3PL activities must obtain a 3PL license for each facility as described in this part and is not required to obtain a license as a wholesale distributor unless it is also conducting wholesale distribution activities, in which case, the entity or facility must obtain both a 3PL license as described in subpart A of this part and a wholesale distributor license as described in subpart C of this part. Unless otherwise noted, the term ''3PL'' or ''third-party logistics provider'' in this part applies to both the entity and the individual facilities requiring a license.

(c) Subpart B of this part applies to any third-party organization seeking to obtain or maintain approval by the Food and Drug Administration (FDA or the Agency) to evaluate the qualifications of 3PLs for licensure. Subpart D of this part applies to any third-party organization seeking to obtain or maintain approval by the Food and Drug Administration to conduct inspections of wholesale distributors.

§ 205.2 Purpose.

The purpose of this part is to establish standards, terms, and conditions for the licensing of 3PLs and prescription drug wholesale distributors by State or Federal licensing authorities, including a process for the revocation, reissuance, and renewal of such licenses. This part also establishes the process and standards the Food and Drug Administration will use to approve third-party organizations to evaluate the qualifications of 3PLs for licensure and conduct inspections of wholesale distributor facilities.

§ 205.3 Definitions.

The definitions and interpretations of terms contained in section 581 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee) apply to those terms when used in this part. The following terms are also defined for purposes of this part:

(a) *3PL activities* means the provision or coordination of warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, while not taking ownership of the product, nor having the responsibility to direct the sale or disposition of the product.

(b) *Change of entity ownership* means:

(1) *Partnership.* In the case of a partnership, the removal, addition, or substitution of a partner.

(2) *Unincorporated sole proprietorship.* In the case of an unincorporated sole proprietorship, the transfer of title and property to another party.

(3) *Corporation.* In the case of a corporation, the merger of the licensed corporation into another corporation or the consolidation of two or more corporations, resulting in the creation of a new corporation. Transfer of corporate stock or the merger of another corporation into the licensed corporation does not constitute change of entity ownership.

(4) *Limited liability company (LLC).* In the case of an LLC, the merger of the licensed LLC into another LLC or the consolidation of two or more LLCs, resulting in the creation of a new LLC. Transfer of company stock or the merger of another LLC into the licensed LLC does not constitute change of ownership.

(c) *Co-licensed partner* means one of two or more entities that have entered a written agreement for the right to engage in the marketing of a prescription drug.

(d) *Designated representative* means an individual who is designated as the representative of the facility manager and is responsible for managing the daily operations of the wholesale distributor or 3PL facility.

(e) *Entity* or *entities* means a business organization, such as a corporation, company, association, firm, partnership, society, sole proprietorship, or joint stock company.

(f) *Facility* means an establishment, warehouse, structure, or structures under common ownership at one general, permanent, physical location used for distribution, including storage and handling, of prescription drugs.

(g) *Key personnel* means any individual who has responsibility for managing the operations of the wholesale distributor, including any principal, owner, director, officer of the wholesale distributor, facility manager, or designated representative, or other individuals who are authorized to enter areas where prescription drugs are held and are likely to handle those prescription drugs as a part their responsibilities within the operation.

(h) *Minimal quantities* means the total annual dollar volume of prescription drugs sold by a retail pharmacy to licensed practitioners for office use does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription drug sales.

(i) *Other logistics services* include services provided by entities that accept or transfer direct possession of products from that entity's facility within the United States and its territories on behalf of a trading partner (*e.g.,* manufacturer, wholesale distributor, dispenser) but that do not take ownership of the product nor have the responsibility to direct a product's sale or disposition. ''Other logistics services'' also means services undertaken with respect to a product for a repackager acting on behalf of a manufacturer, wholesale distributor, or dispenser.

(j) *Other than a consumer* or *patient* means the person receiving the drug is not:

(1) The individual identified as the recipient of the prescription drug;

(2) A dispenser fulfilling a specific patient need as defined in section 581(19) of the Federal Food, Drug, and Cosmetic Act; or

(3) The clinical investigator, as defined in § 312.3(b) of this chapter.

(k) *Product* means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (*e.g.,* capsules, tablets, lyophilized products before reconstitution).

(l) *Significant disciplinary action* means any action by a State or Federal licensing authority that limits or prevents a 3PL from conducting 3PL activities related to the distribution of prescription drugs, or limits or prevents a wholesale distributor from distributing, as that term is defined in section 581(5) of the Federal Food, Drug and Cosmetic Act, or facilitating the distribution of prescription drugs. This includes the revocation or suspension of a 3PL or wholesale distributor license, or of a registration with the Drug Enforcement Administration.

(m) *Unfit for distribution* means a prescription drug that has been identified as a drug whose sale would violate the Federal Food, Drug, and Cosmetic Act. This includes prescription drugs identified as suspect or illegitimate pursuant to section 582(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee–1(c)); adulterated pursuant to section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), including drugs rendered nonsaleable because conditions such as return, recall, damage, or expiry cast doubt on the drug's safety, identity, strength, quality, or purity; or misbranded pursuant to section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

(n) *Wholesale distribution* means the distribution of a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) to a person other than a consumer or patient, or receipt of a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act by a person other than the consumer or patient, but does not include:

(1) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(2) The distribution of a drug or an offer to distribute a drug among hospitals or other health care entities that are under common control;

(3) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d), except that, for purposes of this paragraph (n)(3), a drug shortage not caused by a public health emergency will not constitute an emergency medical reason;

(4) The dispensing of a drug pursuant to a prescription executed in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act;

(5) The distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use;

(6) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(7) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(8) The distribution of a drug by the manufacturer of such drug;

(9) The receipt or transfer of a drug by an authorized 3PL, provided that such 3PL does not take ownership of the drug;

(10) A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(11) The distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e) of the Federal Food, Drug, and Cosmetic Act;

(12) Saleable drug returns when conducted by a dispenser;

(13) The distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in paragraphs (n)(13)(i) through (iv) of this section as a *medical convenience kit*) if:

(i) The medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)(2));

(ii) The medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Controlled Substances Act;

(iii) In the case of a medical convenience kit that includes a product, the person that manufactures the kit:

(A) Purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(B) Did not alter the product's primary container or label as purchased from the manufacturer or wholesale distributor;

(iv) In the case of a medical convenience kit that includes a product, the product is:

(A) An intravenous solution intended for the replenishment of fluids and electrolytes;

(B) A product intended to maintain the equilibrium of water and minerals in the body;

(C) A product intended for irrigation or reconstitution;

(D) An anesthetic;

(E) An anticoagulant;

(F) A vasopressor; or

(G) A sympathomimetic;

(14) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(15) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body (such as dialysis solutions);

(16) The distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) The distribution of medical gas, as defined in section 575 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ddd);

(18) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(19) The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager as described in section 581(16)(B) of the Federal Food, Drug, and Cosmetic Act and registered under section 510 of the Federal Food, Drug, and Cosmetic Act for the purpose of repackaging the drug for use by that hospital or other health care entity, and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

Subpart A—Third-Party Logistics Providers Licensure Standards

§ 205.4 Requirement that third-party logistics providers be licensed.

(a) No 3PL may conduct 3PL activities unless each facility of the 3PL is licensed:

(1) By the State from which the 3PL conducts 3PL activities; or

(2) If the State from which the 3PL conducts 3PL activities has not established a licensure requirement in accordance with the standards set forth in this part, by the Food and Drug Administration; and

(3) If the product is distributed interstate, by the State into which the 3PL distributes the product if such licensure is required by that State, and the 3PL is not licensed by the Food and Drug Administration under § 205.6.

(b) Each facility owned, leased, or rented by a 3PL must have a separate license.

(c) Licenses are facility- and owner-specific and are not transferable.

(d) The 3PL must maintain its license at the licensed facility in a readily retrievable manner and must permit inspection of the license by any official, agent, or employee of the licensing authority or of any Federal, State, or local agency engaged in enforcement of laws relating to the distribution of prescription drugs.

§ 205.5 General application requirements for licensure.

(a) *Applicant requirements.* An individual who submits an application on behalf of a 3PL for a license issued pursuant to this subpart must:

(1) Be 18 years of age or older;

(2) Submit an affidavit that such individual's ownership or management of or employment by the 3PL would not preclude the 3PL from receiving or maintaining a license under § 205.11(f);

(3) Submit all application information required in the form required by the licensing authority; and

(4) Pay any licensing fees that are required by the licensing authority pursuant to section 584(c) of the Federal Food, Drug, and Cosmetic Act.

(b) *General requirements for licensure application.* The State or Federal licensing authority will require the following information from each 3PL facility as part of the initial application for the license described in § 205.4 and as part of any renewal of such license:

(1) The name and title of the individual who submits the application for licensure on behalf of the 3PL;

(2) The name of the 3PL as it should appear on the license, full business address of the facility, and telephone number;

(3) All trade or business names used by the 3PL, including prior trade or business names, within the past 7 years;

(4) Name, email address, and telephone number of the 3PL's facility manager or designated representative;

(5) The type of ownership or operation of the business entity, such as a partnership, corporation, limited liability company, or sole proprietorship;

(6) The name of any owners or operators of the 3PL, including:

(i) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(ii) If a partnership, the name of each partner and the name of the partnership;

(iii) If a corporation, the corporate names, the names of any subsidiaries and affiliates, the name and title of each corporate officer and director, and the State of incorporation; and

(iv) If a limited liability company, the name of the limited liability company, including any subsidiaries and affiliates, the name of each member, and the State in which the limited liability company was organized; and

(7) Whether the 3PL facility manager or designated representative has ever been convicted of a felony relating to prescription drug distribution, including a conviction under section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(i) or (k)) or 18 U.S.C. 1365, relating to product tampering, together with details concerning any such events.

(c) *General requirements for renewal applications.* On the renewal application provided by the State or Federal licensing authority, the 3PL must:

(1) Certify that the 3PL has continued to meet all the standards and complied with the requirements in this subpart since the previous license was issued; and

(2) Inform the applicable licensing authority of any changes to information previously submitted pursuant to paragraph (b) of this section or § 205.6(a)(2) for which a notification was not already submitted to the licensing authority under § 205.7.

§ 205.6 Federal licensure process.

(a) *Procedures for filing an FDA application for a 3PL license.* (1) Each 3PL facility must electronically submit an application to the Food and Drug Administration for a license to conduct 3PL activities in a State if the State does not have a 3PL licensure program consistent with the standards set forth in this section. The application must include the information specified in § 205.5, along with supporting documentation that demonstrates the applicant's storage practices are sufficient to ensure the continued safety, identity, strength, quality, and purity of the products in the facility.

(2) If one or more organizations have been approved by the Food and Drug Administration to conduct a review of a 3PL's qualifications for licensure pursuant to § 205.17, the 3PL will indicate in its application to the Food and Drug Administration which approved organization (AO) it prefers to conduct its licensure review. If there is no organization approved by the Food and Drug Administration to conduct licensure review, the Food and Drug Administration will conduct the review, as described in § 205.17(b). Licensure review must consist of:

(i) Review of all documents submitted in support of the application for 3PL licensure; and

(ii) Inspection of the facility, as directed by the licensing authority pursuant to § 205.16(a) or (b).

(3) The applicant, or the applicant's agent or other authorized official, must sign the application.

(4) An application for a 3PL license will not be considered as filed until the Food and Drug Administration has received all pertinent information and fees.

(b) *Determination that licensing requirements have been met.* The Food and Drug Administration, not an AO, will determine whether the 3PL meets all the applicable requirements set forth in this part.

(c) *Notification of easily correctable deficiencies.* The Food and Drug Administration will make every reasonable effort to promptly communicate to applicants easily correctable deficiencies found in an application when those deficiencies are discovered, particularly deficiencies concerning storage, handling, distribution, or recordkeeping issues. The Food and Drug Administration will also promptly inform applicants of its need for more data or information or for changes in the application needed to facilitate the Agency's review.

(d) *Issuance of 3PL license by FDA.* Approval of a 3PL license application or issuance of a 3PL license constitutes a determination by the Food and Drug Administration that, based upon the information provided and reviewed, the 3PL meets the applicable requirements to be licensed under section 584 of the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration will approve an application and send the applicant an approval letter and license certificate if none of the reasons in § 205.9(a)(1) for refusing to approve the application applies. Applicable requirements for the maintenance of 3PL facilities to conduct 3PL activities will include but not be limited to the good storage practices set forth under § 205.10. A license is effective on the date of issuance of the license certificate.

(e) *Validity of 3PL license.* Licenses issued to 3PL facilities will remain valid until the date of expiration, unless suspended or revoked.

§ 205.7 Changes to information, location, or ownership of a licensed 3PL.

(a) Any change to any information required in this subpart, including changes to any information required pursuant to §§ 205.5, 205.6, 205.11, and 205.15, must be submitted electronically to the licensing authority within 30 calendar days after such change is effective, except where otherwise provided in this subpart.

(b) Any change in the location of a facility at which 3PL activities are conducted will require a new license and inspection of the new facility prior to its beginning operations.

(1) The application for a new license required by § 205.5 must be submitted no later than 90 calendar days prior to beginning operations at the new location.

(2) On the date the change of location takes place, the license for the original facility is void.

(c) Any change in the entity engaged in 3PL activities in a facility will require a new license prior to beginning operations.

(1) The application for a new license required by § 205.5 must be submitted no later than 30 calendar days prior to the change in ownership.

(2) A new inspection of the facility may also be required at the licensing authority's discretion.

(3) A 3PL can continue to operate under the original license for 30 calendar days after the change of ownership occurs or until the license application of the new owner is approved, whichever is sooner.

§ 205.8 Expiry and renewal.

Any license issued or renewed pursuant to § 205.5 or § 205.6 will expire 3 years after the date issued. A 3PL renewal application will not be accepted more than 90 calendar days before the date of expiration. A 3PL will not be penalized for administrative delay on the part of the licensing authority in issuing a new license. A license will be considered valid during the period of the administrative delay if the 3PL timely submitted the renewal application.

§ 205.9 Licensure denial, suspension, reinstatement, revocation, and voluntary termination: notice and opportunity to request a hearing.

(a) *Denial of application for licensure.* (1) The licensing authority will refuse to approve or renew a 3PL license application for any of the following reasons:

(i) The facilities and controls used for the receipt, security, storage, inventory, shipment, or distribution of the product are inadequate to facilitate safe operations pursuant to § 205.10(b).

(ii) The methods or procedures to be used in the receipt, security, storage, inventory, shipment, or distribution of the product do not comply with the requirements for good storage practices in § 205.10.

(iii) The personnel employed by the applicant do not meet the requirements necessary for good storage practices in § 205.11.

(iv) There is insufficient information in the written policies and procedures required in § 205.12 to determine whether the methods or procedures to be used in the receipt, security, storage, inventory, shipment, or distribution of the product comply with the requirements for good storage practices in § 205.10, or to determine whether the facilities and controls to be used in the receipt, security, storage, inventory, shipment, or distribution of the product facilitate safe operations.

(v) The methods or procedures to be used in the receipt, storage, handling, or distribution of the product do not comply with the requirements for adequate recordkeeping in § 205.10 or § 205.13.

(vi) The application contains an untrue statement of material fact.

(vii) The applicant does not permit a properly authorized officer or employee of FDA, a State licensing authority, or an organization approved by the Food and Drug Administration pursuant to § 205.17 an adequate opportunity to inspect the facilities, controls, and any records relevant to the application.

(viii) For renewal applications, failure to report to the licensing authority any pertinent change of information required in § 205.5 or § 205.7.

(ix) For renewal applications, failure to comply with any of the requirements for annual reporting in § 205.15.

(2) If a 3PL's application fails to demonstrate that the 3PL meets the requirements for licensure set forth in this part, the licensing authority will provide written notice to the applicant that its license application may be denied, setting forth the grounds for the denial and an opportunity to demonstrate that the 3PL meets the requirements for licensure.

(3) The notice will inform the applicant of its right to provide additional information and request reconsideration of the denial by the licensing authority within 14 calendar days of the date of the licensing authority's written notice.

(4) If no reconsideration is sought or if, upon reconsideration, the licensing authority denies the applicant's request for licensure, the licensing authority will provide the applicant written notice of the denial and will provide the applicant notice of the opportunity to request a hearing.

(5) The applicant who wishes to request a hearing has 10 calendar days after the date of the notice of denial to submit a written notice of participation and request for a hearing. The applicant who fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(6) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(b) *Suspension of license after notice and opportunity to request a hearing.* (1) The licensing authority may move to suspend a license if the licensing authority has a reasonable belief that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart.

(2) The licensing authority will provide written notice of intent to suspend a 3PL license setting forth the grounds for the suspension pursuant to this part, including what information would be required to demonstrate or achieve compliance. The notice will inform the applicant of its right to provide additional information, request reconsideration of the suspension by the licensing authority, and demonstrate or achieve compliance before suspension.

(3) Each 3PL license holder has 30 calendar days from the date of the notice of intent to suspend to present, in writing, comments and information bearing on the initial decision.

(4) If no comments or information are received within 30 calendar days or if, upon reconsideration, the licensing authority believes the 3PL license should still be suspended, the licensing authority will provide the 3PL a second written notice of the intent to suspend, informing the 3PL of the opportunity to request a hearing on the question of whether there are grounds for suspension.

(5) The written notice will contain a statement that the 3PL will be afforded an opportunity to request a hearing.

(6) The 3PL must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of notice of the intent to suspend. A 3PL that fails to submit

a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing and the license will be suspended.

(7) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(8) If a 3PL's license is suspended and the 3PL does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the 3PL's license.

(c) *Immediate suspension of license.* (1) The licensing authority may suspend a license effective immediately if the licensing authority reasonably believes that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would reasonably be expected to cause an imminent threat to public health.

(2) The licensing authority will provide the 3PL with written notice of immediate suspension of its license setting forth the grounds for the immediate suspension pursuant to this part, including what information would be required to demonstrate compliance, and the opportunity to request a hearing within 10 calendar days of the 3PL's request for such hearing.

(3) The 3PL must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of the written notice of immediate suspension. A 3PL that fails to submit a written notice of participation and request for hearing within 10 calendar days after the date of the written notice waives the opportunity for a hearing.

(4) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(5) If a 3PL's license is suspended and the 3PL does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the 3PL's license.

(d) *Reinstatement of suspended licenses.* The licensing authority may reinstate a previously suspended license upon a 3PL's showing of compliance with requirements in this part and upon such inspection and examination as the licensing authority may require.

(e) *Revocation.* (1) If compliance is not demonstrated or achieved to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the 3PL's license.

(2) The licensing authority will notify the 3PL of the intent to revoke the 3PL's license, setting forth the grounds for the revocation and offering an opportunity to request a hearing on the proposed revocation.

(3) The written notice will contain a statement that the 3PL may request a hearing.

(4) The 3PL must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. A 3PL that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(5) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(f) *Nonrenewal.* If a license is suspended and the 3PL does not submit a renewal application by the date of expiration of the suspended license, the license will be considered expired. A 3PL may not conduct 3PL activities with an expired license and must submit a new application for licensure if it wishes to conduct 3PL activities.

(g) *Voluntary termination of licensure upon request by the 3PL.* The licensing authority will terminate a 3PL facility's license upon the 3PL's request, which includes a notice of intent to discontinue its 3PL activities and waive opportunity for a hearing. A 3PL facility that voluntarily terminates licensure must obtain a new license before resuming 3PL activities.

(1) If a 3PL facility that has had its license revoked wishes to apply for a new license, that facility must submit a new license application, which may include an inspection if required by the licensing authority under § 205.16.

(2) [Reserved]

§ 205.10 Good storage practices for 3PL facilities.

(a) A facility owned, rented, or leased by a 3PL for the purpose of conducting 3PL activities must meet the storage practices for facilities required in paragraphs (b) through (d) of this section.

(b) A facility to which a 3PL license has been issued in the same name and at the same address as another trading partner, such as a wholesale distributor, must maintain separate systems and processes for products that are specific to the 3PL.

(c) A facility owned, leased, or rented by a 3PL in which 3PL activities are conducted must have suitable storage practices in place for such facility, as demonstrated by the following:

(1) *General requirements.* The facility is:

(i) Not a personal residence;

(ii) Of a suitable size, construction, and configuration to ensure proper storage and distribution of all products warehoused at the facility, including lighting, ventilation, temperature, sanitation, humidity, space, equipment, and secure conditions where products are stored;

(iii) Of a suitable size, construction, and configuration to facilitate cleaning, maintenance, proper logistics, and distribution operations, and to provide protection from intrusion; and

(iv) Maintained in a clean and orderly condition, free from infestation of any kind.

(A) A cleaning program schedule must be maintained, documented, and followed.

(B) A pest control program, which is designed to ensure that the facility is free from infestation, must be in place, and pest control records must be kept.

(2) *Areas to handle separation of products that are unfit for distribution.* The facility has:

(i) Clearly defined, designated areas separate from saleable products to quarantine suspect product, illegitimate product, and other products that are unfit for distribution until dispositioned.

(ii) Clearly defined, designated areas to handle separation of products that are returned, recalled, or expired.

(iii) For returned or recalled products, clearly defined, designated areas separate from saleable products to handle returned or recalled product.

(iv) For expired products, clearly defined, designated areas separate from saleable products from which expired product may be returned to the manufacturer or repackager or destroyed.

(3) *Security of premises.* The facility is:

(i) Designed so that designated areas of the facility where products are held are accessible only to personnel, regardless of employee or contractor status, position title, or ownership interest, who possess appropriate and verifiable experience and training necessary to safely and lawfully engage in 3PL activities; and

(ii) Equipped with adequate security to protect from vulnerabilities and potential breaches. Adequate security must include precautions taken to ensure that:

(A) The facility is secure from unauthorized entry;

(B) Access from outside the premises is limited, well controlled, and documented;

(C) The outside perimeter of the premises is well lit;

(D) The facility is equipped with an alarm system to detect and notify appropriate personnel of entry after hours; and

(E) The facility is equipped with a security system that provides suitable protection against theft and diversion of products.

(4) *Facility assessments.* Facility assessments, including temperature mapping and other assessments designed to ensure products are properly stored in accordance with their labeling, must be regularly conducted and documented.

(5) *Equipment.* Equipment must be utilized and maintained in good repair and must be suitable for 3PL activities, as demonstrated by the following:

(i) The 3PL must be able to demonstrate that all equipment has been calibrated, as applicable, and validated at regular intervals to achieve the intended results accurately, consistently, and in a manner that can be reproduced by qualified individuals following approved procedures;

(ii) The 3PL must use appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or logs to document proper storage of products; and

(iii) The monitoring equipment must alert appropriate personnel in a timely manner of any deviations from the intended storage conditions.

(d) In addition to the requirements set forth in this subpart, products must be handled and stored in accordance with all applicable Federal and State laws.

§ 205.11 Personnel requirements necessary for good storage practices.

(a) The 3PL must maintain a list of officers, directors, managers, and designated representatives; a description of their duties; and a summary of their qualifications. This list must be available for review by the State or Federal licensing authority.

(b) Qualifications for the 3PL's facility manager or designated representative of such facility manager must include that the individual:

(1) Has the education, background, training, and experience necessary to perform such individual's assigned functions;

(2) Serves as the facility manager or designated representative of such facility manager for only one facility at a time; and

(3) Is actively involved in and responsible for managing the daily operations of the 3PL facility.

(c) The 3PL must provide the facility manager or designated representative adequate authorities and resources to effectively manage the 3PL's daily operations in accordance with the standards in this part.

(d) The facility manager or designated representative is responsible for managing all the daily operations of the 3PL facility, including those duties delegated to other personnel.

(e) A 3PL is prohibited from obtaining or maintaining licensure if the 3PL employs a facility manager or designated representative who has been:

(1) Convicted of any felony violation of section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act; or

(2) Convicted of any violation of 18 U.S.C. 1365, relating to product tampering.

(f) Licensure may also be denied when storage practices are not sufficient to maintain adequate security because a facility manager or designated representative of such facility manager has been:

(1) Found to have delayed or otherwise impeded an inspection by the Federal or State licensing authority or an approved third-party inspector, or if an inspector, after reasonable efforts, was unable to gain access to an establishment or a location to carry out the inspection required under § 205.16 as permitted by section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a));

(2) Found to have omitted material information or furnished false or fraudulent information in an application made in connection with the distribution of prescription drugs; or

(3) Subject to licensure suspension or revocation by Federal, State, or local government for any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances.

(g) Any facility manager or designated representative will be subject to criminal background checks. The results of the background checks must demonstrate no history of criminal convictions pursuant to paragraph (e) of this section.

§ 205.12 Required written policies and procedures.

(a) *General requirements for written policies and procedures.* Every 3PL must establish, maintain, and follow written policies and procedures as described in this section and relevant to the scope of their 3PL activities. The written policies and procedures must clearly delineate the responsibilities of the 3PL and any contractors used to fulfill any of the 3PL's duties. The written policies and procedures must also describe a system by which the 3PL will monitor all processes and, if deviations occur, document and investigate to determine the root cause of the deviation in a timely manner. Such written policies and procedures must be made available to the licensing authority upon request, and the licensing authority may copy records to ensure the 3PL is following written policies and procedures.

(1) Written policies and procedures must include, but are not limited to, the following:

(i) Documentation pertaining to receipt, security, storage, handling, inventory, shipment, and distribution of products, including written policies and procedures for identifying, recording, and reporting confirmed losses, thefts, diversions, and products unfit for distribution; and

(ii) Documentation pertaining to all policies, procedures, instructions, contracts, data, inspection reports, and any other documentation related to compliance with this part.

(b) *Personnel.* The 3PL must establish, maintain, and follow written policies and procedures that ensure the qualifications of personnel are met, maintained, and documented as required in § 205.11. These written policies and procedures must be available for review by the State or Federal licensing authority, as provided in § 205.13.

(c) *Written policies and procedures.* The 3PL must maintain written policies and procedures to address receipt, security, storage, inventory, shipment, and distribution of the product.

(1) *Receipt.* The 3PL must establish, maintain, and follow written policies and procedures providing for the inspection of all shipping containers in accordance with the following standards:

(i) *Incoming shipments.* Upon receipt, each shipping container must be visually examined for identity and for conditions that would suggest the product may be unfit for distribution.

(ii) *Outgoing shipments.* Each outgoing shipment must be properly inspected for identity of the product and to ensure that there is no shipment of product that is unfit for distribution.

(2) *Security.* The 3PL must establish, maintain, and follow written policies and procedures that provide for the secured storage of products and preserve the integrity of the 3PL's data and records.

(3) *Storage.* The 3PL must establish, maintain, and follow written policies and procedures that ensure products are stored at appropriate temperatures and under appropriate conditions, in accordance with the requirements in the products' labeling, to preserve their identity, strength, quality, and purity.

(4) *Inventory.* The 3PL must establish, maintain, and follow written policies and procedures related to inventory controls that:

(i) Ensure the facility's stock is inventoried regularly to protect against diversion and against distribution of product that may be unfit for distribution;

(ii) Contain procedures to identify, investigate, document, and correct stock errors, inaccuracies, and irregularities, including product theft, loss, or diversion;

(iii) Identify, record, and report confirmed product losses or theft immediately to the owner of the products and relevant authorities; and

(iv) Ensure that the 3PL can trace the receipt and outbound distribution of a product, as well as maintain supply and inventory records.

(5) *Shipment.* The 3PL must establish, maintain, and follow written policies and procedures providing for the transportation of products in accordance with the following standards:

(i) Products must be transported in a manner that will:

(A) Protect against breakage, contamination, adulteration, and theft;

(B) Prevent exposure to conditions that may compromise their quality and integrity; and

(C) Ensure that deviations from storage requirements during transport are promptly identified, investigated, documented, and reported to the trading partner from whom the product was received and to the manufacturer to determine if further commercial distribution is appropriate.

(ii) A 3PL that outsources transportation of products to a transportation provider, such as a common carrier, remains responsible for compliance with this part while the products are in transit to the intended trading partner. Arrangements for transportation by a transportation provider must be documented and carried out in accordance with the requirements in this section.

(6) *Distribution.* The 3PL must establish, maintain, and follow written policies and procedures related to the distribution of products that:

(i) Ensure products are distributed at appropriate temperatures and under appropriate conditions in accordance with the requirements in the products' labeling to preserve their identity, strength, quality, and purity; and

(ii) Protect against diversion and against distribution of products that may be unfit for distribution.

(d) *Recalled products.* The 3PL must establish, maintain, and follow written policies and procedures to support manufacturer recalls.

(e) *Preparing for foreseeable crises.* The 3PL must establish, maintain, and follow written policies and procedures to prepare for, protect against, and address any reasonably foreseeable crises that could affect security or operations (such as strike, fire, or flood).

(f) *Products that are unfit for distribution.* The 3PL must establish, maintain, and follow written policies and procedures for handling products that are adulterated, misbranded, or otherwise unfit for distribution, as well as returned products, that:

(1) Require such products to be physically segregated from other products and dispositioned as directed by the applicable manufacturer, wholesale distributor, dispenser, or an authorized government agency and in accordance with all applicable State and Federal laws;

(2) Identify a contact person responsible for communicating with the manufacturer, wholesale distributor, dispenser, or an authorized government agency regarding nonsaleable and returned products;

(3) Include procedures to prevent products unfit for distribution from entering the supply chain through the 3PL's disposition of nonsaleable products; and

(4) Require the 3PL to document the disposition of all nonsaleable and returned products, and maintain such records for inventory accountability.

(g) *Suspect product.* The 3PL must establish, maintain, and follow written policies and procedures to quarantine or destroy a suspect product if directed to do so by the product's manufacturer, wholesale distributor, dispenser, or an authorized government agency.

(h) *Illegitimate product.* The 3PL must establish, maintain, and follow written policies and procedures to store illegitimate product in a clearly defined, designated area from which the product may be dispositioned as directed by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

§ 205.13 Recordkeeping and document maintenance.

(a) *Maintenance, availability, and accuracy of records and written policies and procedures.* All required records and written policies and procedures outlined in § 205.12 must:

(1) Be readily retrievable and made available to licensing authorities upon request;

(2) Be securely stored from unauthorized access or modifications;

(3) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration; and

(4) Accurately reflect the name of the 3PL as it appears on the 3PL facility's license, which must match the information that is reported to the Food and Drug Administration pursuant to the Food and Drug Administration reporting requirements at § 205.15.

(b) *Record and document retention.* (1) Except for the records listed in paragraph (b)(2) of this section, all records and written policies and procedures required to be maintained by this part must be retained for a period of 3 years.

(2) Records of suspect and illegitimate products and destroyed, returned, and recalled products must be retained for a period of 6 years.

§ 205.14 3PLs must provide upon request a list of trading partners.

A list of all manufacturers, wholesale distributors, repackagers, and dispensers for which the 3PL conducts 3PL activities must be readily retrievable and made available to regulatory authorities upon request.

§ 205.15 Requirements for initial and annual reporting to the Food and Drug Administration.

(a) *Electronic reporting requirement.* The 3PL must report electronically to the Food and Drug Administration using a secure mechanism in a format the Food and Drug Administration can review, process, and archive. Information reported will be included in the Food and Drug Administration's public database for 3PLs to the extent allowable by law.

(b) *Reporting periods*—(1) *Initial reporting.* Any entity that owns or operates a facility that conducts 3PL activities must report to the Food and Drug Administration within 30 calendar days of obtaining an initial State or Federal 3PL license.

(2) *Annual reporting.* Any entity that owns or operates a facility that is licensed to engage in 3PL activities must report to the Food and Drug Administration each calendar year between January 1 and March 31.

(c) *Required information.* Information reported for each 3PL facility separately

licensed by the licensing authority must include:

(1) A complete list of States by which the 3PL facility is licensed, including the corresponding identification number and the expiration date of each such license;

(2) Name of company as it appears on the license and full business address; and

(3) All trade names or business names under which the 3PL conducts business.

(d) *Timing for significant disciplinary action reporting*—(1) *Initial reporting.* The 3PL must report to the Food and Drug Administration any significant disciplinary actions that occurred in the previous 12 months.

(2) *Subsequent reporting.* The 3PL must, within 30 calendar days of a final action taken by a State or Federal licensing authority, report significant disciplinary actions to the Food and Drug Administration.

(e) *Reporting voluntary withdrawal of a State license.* The 3PL must report to the Food and Drug Administration that it has withdrawn its license in a State within 30 calendar days after such withdrawal, including the reasons for the voluntary withdrawal of licensure.

§ 205.16 Inspections.

(a) A physical inspection of a facility owned, rented, or leased by a 3PL for conducting 3PL activities must be conducted prior to issuance of the initial license by the licensing authority.

(1) Where the State is the licensing authority, the State may conduct the inspection or may accept an inspection by a third-party accreditation or inspection service approved by the State licensing authority. If the facility is out of state, the State may conduct the inspection or may accept an inspection by the State in which the facility is located.

(2) Where the Food and Drug Administration is the licensing authority, the Food and Drug Administration may conduct the inspection or may accept an inspection by an organization approved by the Food and Drug Administration under § 205.18.

(b) Routine inspections must be conducted thereafter once every 3 years by the licensing authority, a third-party approved organization or inspection service approved by the Food and Drug Administration under § 205.18, or the State licensing the 3PL.

(c) Records described in § 205.12(a)(1) that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within 2 business days of a request by a State or Federal official, or sooner if necessitated by the duration of the inspection.

(d) The 3PLs must permit the Federal or State licensing authority and third-party approved organizations or inspection services approved by the Food and Drug Administration or the State to enter and inspect their facilities and to audit their records and written operating procedures.

Subpart B—Approved Organizations for 3PLS

§ 205.17 Use of approved third-party organizations.

(a) A third-party organization that has been approved by the Food and Drug Administration pursuant to § 205.18 (or ''approved organization'' (AO)) may conduct licensure review of a 3PL's qualifications for licensure and may conduct inspections of 3PLs at the periodic intervals specified in § 205.16, as directed by the Food and Drug Administration.

(b) If an organization has been approved by the Food and Drug Administration to conduct licensure review, the AO will:

(1) Conduct the licensure review, which consists of:

(i) Reviewing all documents submitted in support of the application for 3PL licensure; and

(ii) Inspecting the facility, as directed by the licensing authority;

(2) Complete the licensure review within a timeframe not to exceed 90 calendar days after receiving notice to conduct a licensure review from the Food and Drug Administration;

(3) Based on the licensure review, write a detailed document including any findings and observations in support of the AO's recommendation to the Food and Drug Administration to grant or deny licensure; and

(4) Send the original document to the Food and Drug Administration, with a copy to the 3PL, within 7 calendar days of completing the licensure review.

(c) When conducting routine inspections at periodic intervals, the AO will:

(1) Complete the inspection within a timeframe not to exceed 90 calendar days after receiving notice to conduct an inspection from the Food and Drug Administration;

(2) Based on the inspection, write a detailed document including any findings and observations in support of the AO's recommendation to the Food and Drug Administration regarding a 3PL's licensure; and

(3) Send the original document to the Food and Drug Administration, with a copy to the 3PL, within 7 calendar days of completing the inspection.

(d) To maintain approval, an organization approved by the Food and Drug Administration must:

(1) Maintain records that support the AO's initial and continuing qualifications for approval for a minimum of 5 years;

(2) Maintain the following records related to licensure reviews for a minimum of 5 years:

(i) Supporting documentation reviewed as part of a licensure review;

(ii) Licensure review and inspection reports;

(iii) Correspondence with the Food and Drug Administration and the 3PL associated with a licensure review; and

(iv) Information on the identity and qualifications of all AO personnel who contributed to the licensure review, including a certification that such personnel have complied with all applicable requirements set forth in subpart A of this part and are free of any conflicts of interest, as set forth at 5 CFR part 2635 and 18 U.S.C. 208.

(e) Records maintained by the AO must:

(1) Be readily retrievable and made available to Federal licensing authorities upon request;

(2) Be maintained and protected in accordance with all applicable laws, including those regarding protection of personal identifying information and confidential commercial information;

(3) Be secure from unauthorized access or modifications; and

(4) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.

(f) An AO must report to the Food and Drug Administration within 24 hours of discovering any evidence or observations of potential violations found at a 3PL facility during an inspection of the facility that could pose an imminent threat to the public health. Reports must be made in the manner prescribed by the Food and Drug Administration.

§ 205.18 General qualifications of approved organizations.

(a) To become and remain an AO, the organization and anyone employed by the organization, including contractors used by the organization:

(1) Must not be a current Federal or State government employee;

(2) Must not engage in prescription drug-related activities, excluding

participation in the Agency's AO program and related activities, but including and not limited to manufacturing, wholesale distribution, repackaging, relabeling, dispensing, or 3PL activities;

(3) Must disclose to the Food and Drug Administration any participation or financial interest in entities that participate in the design, manufacture, promotion, or sale of articles or activities that are predominantly FDA-regulated or are expected to result in FDA-regulated articles;

(4) Must not be owned or controlled by, or have any organizational, material, or financial affiliation with, any of the entities engaged in manufacturing, wholesale distribution, repackaging, relabeling, dispensing, 3PL activities, or the design, manufacture, promotion, or sale of prescription drugs as defined in section 581(12) of the Federal Food, Drug, and Cosmetic Act;

(5) Must enter and abide by a written agreement with the applicant before data and information otherwise exempt from public disclosure may be disclosed to the AO or a contractor;

(6) Must operate in accordance with professional and ethical business practices and applicable legal requirements, which include, but are not limited to:

(i) Protecting against conflicts of interest as set forth in 5 CFR part 2635 and 18 U.S.C. 208;

(ii) Ensuring that the personnel employed or contracted by the AO who are working on licensure reviews have sufficient education, training, knowledge, and experience to conduct licensure reviews of 3PLs;

(iii) Treating received information, records, and reports that qualify as confidential commercial information as described at 5 U.S.C. 552(b)(4) according to applicable requirements for such information;

(iv) Maintaining appropriate security and protection, physical and electronic, of any information received in relation to licensure reviews to preserve confidentiality and ensure that the release of any information is limited to authorized disclosures to either the Food and Drug Administration or the 3PL facility;

(v) Reporting information to the Food and Drug Administration and entities for which licensure reviews were conducted that accurately reflects data reviewed, inspectional observations made, and other matters that relate to compliance with the Federal Food, Drug, and Cosmetic Act; and

(vi) Promptly responding to and attempting to resolve any complaints regarding activities for which it is approved by the Food and Drug Administration; and

(7) Must establish and maintain policies, procedures, and documentation to demonstrate that, at the time of application and throughout their tenure as an AO, the applicant has satisfied and can continue to satisfy the requirements to qualify as an AO capable of assessing compliance with all 3PL requirements. Such policies, procedures, and documentation must include, but are not limited to:

(i) AO program administration;

(ii) Disciplinary actions and corrective measures;

(iii) Recordkeeping and confidentiality;

(iv) Use of contractors; and

(v) Personnel qualifications and ongoing training.

(b) If an AO elects to use contractors for licensure reviews or licensure review-related activities, the AO remains responsible for the work of the contractors at all times.

(1) AOs that use contractors to conduct licensure reviews must abide by the confidentiality agreements between the Food and Drug Administration and the AO and have policies and procedures in place to ensure the contractor's continuing compliance with this part, as well as competence and qualifications to conduct licensure reviews. Such policies and procedures must ensure that contractors:

(i) Meet the qualifications set forth in paragraph (a) of this section;

(ii) Do not subcontract their licensure review duties, and that contractors are removed if such requirement is violated;

(iii) Abide by the policies and procedures of the AO, as set forth in § 205.19(b); and

(iv) Complete and pass the same training required by the AO, as set forth in § 205.19(c).

(2) If an AO elects to use contractors to conduct licensure reviews, the AO must receive and keep a record of written consent from the 3PL to share confidential commercial information with contractors by which a licensure review is being conducted.

(3) AOs that elect to use contractors must submit to the Food and Drug Administration a list of contractors used by the organization, accompanied by a statement from the organization certifying that such contractors meet the requirements of this subpart.

§ 205.19 Process and procedures for approval by the Food and Drug Administration.

(a) *Application.* An application to become an AO must be completed and submitted electronically to the Food and Drug Administration in a format the Food and Drug Administration can review, process, and archive.

(b) *Required application information.* Policies, procedures, and documentation as required by § 205.18(a)(7) must accompany the application.

(c) *Training.* Organizations must provide training as prescribed by the Food and Drug Administration, and any individual who conducts licensure reviews or supervises individuals who conduct licensure reviews is required to undergo and pass the prescribed training.

(1) If an individual does not pass training, that person must wait 30 days before retaking the training and may be required to show proof of additional education or experiential learning to demonstrate competence before retaking the training evaluation.

(2) To maintain approval, individuals employed by the AO and conducting licensure reviews or supervising those who conduct licensure reviews must undergo and pass annual training as prescribed by the Food and Drug Administration. Failure to complete and pass annual training may result in suspension of approval of the AO.

(3) The Food and Drug Administration may require additional training. If such additional training is required, AOs will be given a set time period during which training must be completed and passed to maintain approval.

(d) *Auditing.* Prior to conducting licensure reviews, an AO must undergo an onsite audit by the Food and Drug Administration. The Food and Drug Administration may also conduct random, periodic audits, as well as for-cause audits, of an AO, as set forth in paragraph (o) of this section.

(e) *Duration of approval and renewal process.* (1) The Food and Drug Administration approval to conduct licensure reviews is valid for a period of 5 years.

(2) AOs may submit a renewal application to the Food and Drug Administration 6 months prior to the expiration date, but no later than 3 months prior to the expiration date, to renew the approval.

(i) If a renewal application is submitted less than 3 months before the date of expiration, the AO's approval will expire if approval is not renewed prior to the date of expiration.

(ii) Upon expiration of the AO's approval, the AO must cease conducting any licensure review or inspection-related activities.

(f) *Denial of approval.* If an organization does not meet all of the Food and Drug Administration's standards detailed in §§ 205.17 and 205.18 for becoming an AO, the Food and Drug Administration will deny approval of the application in writing. Requests for review and reconsideration of a denial of approval must be submitted to the Food and Drug Administration within 30 calendar days of the date of the Food and Drug Administration's decision to deny the application. If, upon reconsideration, the Food and Drug Administration denies the applicant's request for approval, the Food and Drug Administration will provide the applicant written notice of the denial and an opportunity to appeal pursuant to § 10.75 of this chapter.

(g) *Suspension of approval after notice and opportunity to request a hearing.* (1) The Food and Drug Administration may suspend approval of an organization after an opportunity to request a hearing when there is a reasonable probability that the organization's noncompliance will negatively impact public health.

(2) If an AO fails to maintain the Food and Drug Administration's standards pursuant to §§ 205.17 and 205.18, the Food and Drug Administration will give written notice of the intent to suspend the organization's approval, including the grounds for the suspension, and the AO will have 30 days to provide additional information to the Food and Drug Administration for reconsideration.

(3) If, upon reconsideration, the Food and Drug Administration still believes the AO's approval should be suspended, the Food and Drug Administration will issue the AO a written formal notice of intent to suspend, along with notice of the opportunity to request a hearing pursuant to part 16 of this chapter.

(4) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of intent to suspend to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days from the date of the notice waives the opportunity for a hearing.

(5) A suspended AO must notify any 3PLs under a pending licensure review by the AO of the AO's suspension within 7 calendar days.

(h) *Immediate suspension of approval.* (1) When there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans, the Food and Drug Administration will suspend an AO's approval effective immediately.

(2) In such a situation, the Food and Drug Administration will provide the AO a written notice of immediate suspension, along with notice and opportunity to request a hearing pursuant to part 16 of this chapter within 14 calendar days of the AO's request for such hearing.

(3) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of suspension to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(i) *Reinstatement of approval.* (1) An organization's approval may be reinstated if the Food and Drug Administration determines that the suspended organization has rectified the issues leading to the suspension and can meet the standards set forth in this subpart. The organization must rectify the issues and come into compliance with the standards set forth in this subpart within 1 year from the date of suspension. If the issues have not been rectified within 1 year, or if the organization otherwise has failed to come into compliance with the standards set forth in this subpart within such time period, the Food and Drug Administration may revoke the AO's approval subject to the provisions of this part.

(2) An organization whose approval has been reinstated on a conditional basis will be subject to a 3-year probationary period, and if any material deficiencies arise during that period, the organization's approval will be revoked.

(j) *Revocation of approval.* (1) The Food and Drug Administration may revoke approval of an organization whose approval has been suspended pursuant to paragraphs (g) and (h) of this section:

(i) If an organization fails to demonstrate its intent to rectify the issues leading to the suspension within 6 months from the date of suspension; or

(ii) If the Food and Drug Administration determines that the organization failed to rectify the issues leading to the suspension to the Agency's satisfaction within 1 year of the date of suspension.

(2) The Food and Drug Administration will give written notice of the intent to revoke the organization's approval, including the grounds for the revocation, and an opportunity to request a hearing pursuant to part 16 of this chapter.

(3) The AO must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. An AO that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(4) An organization whose approval has been revoked that wishes to reapply to be an AO must submit a new application to the Food and Drug Administration.

(k) *Requests for reconsideration of Agency decision.* (1) The Food and Drug Administration will follow the process outlined at § 10.75 of this chapter to review matters relating to denial of approval, including review of the organization's application.

(2) The Food and Drug Administration will follow the process outlined at part 16 of this chapter to review matters relating to a suspension or revocation action, including review of the organization's application and administrative file.

(3) The Food and Drug Administration's decision after a request for reconsideration of denial, suspension, or revocation constitutes a final Agency action under 5 U.S.C. 702.

(l) *Voluntary withdrawal of approval.* (1) An organization wishing to voluntarily withdraw its approval, including but not limited to when an AO goes out of business, must notify the Food and Drug Administration in writing at least 6 months prior to the date the organization intends for the withdrawal to become effective.

(i) If an AO determines it will be withdrawing its approval with the Food and Drug Administration in less than 6 months, it must notify the Food and Drug Administration immediately of its intent to withdraw, and such notification must inform the Food and Drug Administration of the date the organization will cease business operations.

(ii) [Reserved]

(2) No later than 7 calendar days after notifying FDA, the organization must notify any facilities with pending reviews that it intends to withdraw its approval with the Food and Drug Administration and must provide the date on which the withdrawal is effective.

(m) *AO-required notifications to 3PLs.* The AO must, within 7 calendar days of the date of suspension, revocation, or voluntary withdrawal of approval, notify those 3PL facilities that have pending licensure reviews of the AO's suspension or revocation. This

notification must inform the 3PL facility that it must apply for licensure review with another AO, or the Food and Drug Administration if no other AO is available to conduct the licensure review.

(n) *Change of operation or ownership.* (1) The AO must report to the Food and Drug Administration within 30 calendar days any changes to the information submitted in the application for approval.

(2) Approval is not transferable.

(i) Changes in ownership of an AO require the organization to submit a new application to the Food and Drug Administration.

(ii) Such application must be submitted to the Food and Drug Administration no later than 30 calendar days prior to the date of the change of ownership.

(iii) No later than 30 calendar days before the date of the change of ownership, the AO must notify any 3PL facilities with pending applications of the pending change in ownership.

(iv) On the date the change of ownership takes place, the original approval is void.

(o) *Monitoring by the Food and Drug Administration.* (1) AOs are subject to audits by the Food and Drug Administration to ensure compliance with the Food and Drug Administration's requirements for approval.

(2) If an AO refuses to cooperate with the Food and Drug Administration's audit, the organization's approval may be suspended pursuant to paragraph (g)(1) of this section.

Subpart C—Wholesale Distributors Licensure Standards

§ 205.20 Requirement that prescription drug wholesale distributors be licensed.

(a) No wholesale distributor may engage in wholesale distribution of a prescription drug unless the person is licensed:

(1) By the State from which the drug is distributed; or

(2) If the State from which the drug is distributed has not established a licensure requirement in accordance with the standards set forth in this part, by the Food and Drug Administration; and

(3) If the drug is distributed interstate, by the State into which the drug is distributed if such licensure is required by that State.

(b) Any license issued or renewed pursuant to this section will expire 2 years after the date on which the license was issued. A wholesale distributor may submit a renewal application up to 90 calendar days before the date of expiration. A license will be considered valid during any period of the administrative delay on the part of the licensing authority, if the wholesale distributor timely submitted the renewal application.

§ 205.21 Surety bond requirement.

(a) *Surety bond compliance.* No wholesale distributor will be licensed under this section unless the wholesale distributor has furnished a bond, or other equivalent means of security acceptable to the State if the State is the licensing authority, that complies with the requirements of this section.

(b) *Surety bond requirements.* (1) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government-owned and -operated wholesale distributor must submit to the licensing authority a surety bond from an authorized surety company of $100,000 or other equivalent means of security acceptable to the State. The term of the initial surety bond must be effective on the date that the application is submitted to the licensing authority.

(2) The licensing authority may accept a surety bond from an authorized surety company in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesale distributor are $10,000,000 or less.

(3) If a wholesale distributor can provide evidence that it possesses the required bond in the State where the wholesale distributor is located, the requirement for a bond in another State for a non-resident wholesale distributor license will be waived.

(c) *Terms of the surety bond.* (1) The terms of the bond submitted by a wholesale distributor must on its face reflect the requirements of this section, including meeting the requirements of liability coverage ($100,000 or $25,000, as applicable), as well as the responsibilities of the surety company and wholesale distributor as set forth in this section.

(2) The bond must be continuous and remain in full force and effect, running concurrently with the license period and for every succeeding licensing period for which the wholesale distributor may be licensed. The bond must remain in full force and effect until 1 year after the license expires, after which liability for license administrative fees ceases except as to any liability or indebtedness incurred or accrued before the termination date.

(3) The bond must guarantee that after receiving written notice from the licensing authority containing sufficient evidence to establish the surety's liability under the bond, the surety company will pay within 30 calendar days any administrative fines or penalties imposed by the licensing authority on the wholesale distributor holding the surety bond in that State. This includes any fees and costs incurred by the licensing authority regarding that license authorized by law and which the wholesale distributor fails to pay within 30 calendar days after the fine or costs become final. Any such claim may be made directly to the surety company and need not be preceded by the filing of any action in a proper court.

(4) The licensing authority may make a claim against the surety bond until 1 year after the date of expiration on the wholesale distributor's license or until 60 calendar days after any administrative or legal proceeding, which involved the wholesale distributor, is concluded, including any appeal, whichever occurs later.

(d) *Cancellation of a bond and lapse of surety bond coverage.* (1) A wholesale distributor may cancel its surety bond and must provide written notice 30 calendar days before the effective date of the cancellation to all applicable licensing authorities and the surety company.

(2) Cancellation of a surety bond is grounds for suspension of the wholesale distributor's license unless the wholesale distributor provides a new bond before the effective date of the bond's cancellation. If a new surety bond is provided before the effective date of the bond's cancellation, the liability of the surety company continues until the cancellation date. Otherwise, the liability of the surety company continues for 1 year after the date of cancellation, after which liability ceases except as to any liability or indebtedness incurred or accrued before the cancellation date.

(3) The wholesale distributor must immediately notify the licensing authority if there is a lapse in the wholesale distributor's surety coverage.

(4) If the licensing authority discovers a lapse in bond coverage that has not been previously disclosed by the wholesale distributor, the wholesale distributor's license will be suspended pursuant to § 205.30.

(e) *Actions under the surety bond.* The bond must provide that actions under the bond may be brought by a State or Federal licensing authority.

(f) *Required surety company information on the surety bond.* The bond must provide the surety company's name, street address or post office box number, city, State, and zip code.

(g) *Change of surety company.* A wholesale distributor that obtains a replacement surety bond from a different surety company to cover the remaining term of a previously obtained bond must submit the new surety bond to the licensing authority 30 calendar days prior to the expiration of the previous surety bond. There must be no gap in the coverage of the surety bond periods.

(h) *Parties to the surety bond.* The surety bond must name the wholesale distributor as Principal, the licensing authority as obligee, and the surety company (and its heirs, executors, administrators, successors, and assignees, jointly and severally) as surety.

§ 205.22 General application requirements for licensure.

(a) *Applicant requirements.* An individual who submits an application on behalf of a wholesale distributor for a license issued pursuant to this subpart must:

(1) Be 18 years of age or older;

(2) Submit an affidavit that their ownership or management of or employment by the entity would not preclude the entity from receiving or maintaining a license under § 205.25(a);

(3) Submit all application information required in the form required by the licensing authority; and

(4) Pay any licensing fees that are required by the licensing authority pursuant to section 503(e)(3) of the Federal Food, Drug, and Cosmetic Act.

(b) *Surety bond requirement.* The wholesale distributor must furnish a bond, or other equivalent means of security acceptable to the State, with the application for licensure in accordance with the surety bond requirements in § 205.21.

(c) *General requirements for licensure application.* The State or Federal licensing authority will require the following information from each wholesale distributor as part of the initial application for the license described in this section and as part of any renewal of such license:

(1) The name and title of the individual who submits the application for licensure on behalf of the wholesale distributor;

(2) The name of the wholesale distributor as it should appear on the license and the full business address and telephone number of the wholesale distributor;

(3) All trade or business names used by the wholesale distributor, including prior trade or business names, within the past 7 years;

(4) Name, email address, and telephone number of the designated representative or facility manager for the wholesale distributor;

(5) The type of ownership or operation of the business entity, such as a partnership, corporation, limited liability company, or sole proprietorship;

(6) The name of any owners or operators of the wholesale distributor, including:

(i) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(ii) If a partnership, the name of each partner and the name of the partnership;

(iii) If a corporation, the corporate names, the names of any subsidiaries and affiliates, the name and title of each corporate officer and director, and the State of incorporation; and

(iv) If a limited liability company, the name of the limited liability company, including any subsidiaries and affiliates, the name of each member, and the State in which the limited liability company was organized;

(7) Whether the wholesale distributor has ever been convicted of a felony relating to wholesale drug distribution, a felony conviction of section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act, or a felony conviction of 18 U.S.C. 1365, relating to product tampering, together with details concerning any such events; and

(8) Whether the wholesale distributor has received any citations for violating requirements for licensure within the past 7 years or has received any significant disciplinary actions within the past 7 years that presented a threat of serious adverse health consequences or death to humans, together with details concerning any such events.

(d) *General requirements for licensure renewal.* To renew a license, the wholesale distributor must submit the following to the renewing licensing authority:

(1) Certification that the wholesale distributor has continued to meet all the standards and complied with the requirements in this subpart since the previous license was issued; and

(2) Information about any changes to information previously submitted under this section, or § 205.21, or § 205.23(c) for which a notification was not already submitted to the licensing authority under § 205.24.

(e) *License availability requirement.* The wholesale distributor must maintain its license in a readily retrievable manner and must permit inspection of the license by any official, agent, or employee of the licensing authority or of any Federal, State, or local agency engaged in enforcement of laws relating to the distribution of prescription drugs.

§ 205.23 Federal licensure process.

(a) *Procedures for filing an FDA application for a wholesale distributor license.* (1) All wholesale distributors must electronically submit an application to the Food and Drug Administration for a license to engage in wholesale distribution if the State does not have a licensing program for wholesale distributors consistent with the standards set forth in this section. The application must include the information in §§ 205.21 and 205.22, along with a surety bond and supporting documentation that demonstrates the applicant's ability to comply with requirements intended to ensure the continued safety, identity, strength, quality, and purity of the prescription drugs.

(2) If one or more organizations have been approved by the Food and Drug Administration under § 205.32 to conduct inspections of wholesale distributors, the wholesale distributor will indicate in its application to the Food and Drug Administration which AO it prefers to conduct its inspection.

(3) If there is no organization approved by the Food and Drug Administration to conduct inspections for wholesale distributors, the Food and Drug Administration will conduct the inspection, as described in § 205.28(b).

(4) The applicant, or the applicant's agent or other authorized official, must sign the application.

(5) An application for a wholesale distributor license will not be considered as filed until the Food and Drug Administration has received all required information and fees.

(b) *Determination that licensing requirements have been met.* The Food and Drug Administration, not an AO, will determine whether the wholesale distributor meets all the applicable requirements set forth in this part.

(c) *Notification of easily correctable deficiencies.* The Food and Drug Administration will make reasonable efforts to promptly communicate to applicants easily correctable deficiencies found in an application when those deficiencies are discovered. The Food and Drug Administration will also promptly inform applicants if more data or information is needed to facilitate the Agency's review.

(d) *Issuance of wholesale distributor license by FDA.* Approval of a wholesale distributor license application or issuance of a wholesale distributor license constitutes a determination by the Food and Drug Administration that, based upon information received, the

wholesale distributor meets the applicable requirements to be licensed under sections 503(e)(1) and 583 of the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration will approve an application and send the applicant an approval letter and license certificate if none of the reasons in § 205.30(a)(1) for refusing to approve the application applies. Applicable requirements for wholesale distributors to engage in wholesale distribution must include but not be limited to the good storage practices set forth under § 205.26. A license is effective on the date of issuance of the license certificate.

(e) *Validity of a wholesale distributor license.* Licenses issued to a wholesale distributor will remain valid until the date of expiration, unless suspended or revoked.

§ 205.24 Changes to information, operation, location, or ownership of a wholesale distributor.

(a) Any change to any information required in this subpart, including changes to any information required pursuant to §§ 205.21, 205.22, and 205.25, must be submitted electronically to the licensing authority within 30 calendar days after such change is effective, except where otherwise provided in this subpart.

(b) Any change in the location of a wholesale distributor at which wholesale distribution occurs will require an inspection of the new facility prior to the wholesale distributor beginning operations at the new facility.

(1) On the date the change of location takes place, the wholesale distributor may not engage in wholesale distribution at the original facility.

(2) [Reserved]

(c) Any change in the person engaged in wholesale distribution will require a new license prior to beginning operations.

(1) The application for a new license required by § 205.23 must be submitted no later than 30 calendar days prior to the change in ownership.

(2) A new inspection of the wholesale distributor will be performed within a reasonable time.

(3) A wholesale distributor can continue to operate under the original license for 30 calendar days after the change of ownership occurs or until the license application of the new owner is approved, whichever is sooner.

§ 205.25 Prohibited persons and qualifications for key personnel.

(a) A wholesale distributor is prohibited from obtaining or maintaining licensure if the wholesale distributor has been:

(1) Convicted of any felony for violation of section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act;

(2) Convicted of any felony violation of 18 U.S.C. 1365 relating to product tampering; or

(3) Cited on two or more occasions within the previous 7 years for violating one or more of the requirements of section 583 or section 503(e) of the Federal Food, Drug, and Cosmetic Act or State requirements for licensure in such a way that presents a threat of serious adverse health consequences or death to humans.

(b) All key personnel must have the education, background, training, and experience necessary to perform his or her assigned functions.

(c) Licensure may also be denied when an applicant wholesale distributor or any of their key personnel has been:

(1) Found to have delayed or otherwise impeded an inspection by the Federal or State licensing authority or an approved third-party inspector, or an inspector, after reasonable efforts, was unable to gain access to an establishment or a location to carry out the inspection required under § 205.28, as permitted by section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a));

(2) Found to have omitted material information or furnished false or fraudulent information in an application made about the distribution of prescription drugs; or

(3) Subject to licensure suspension or revocation by Federal, State, or local government for any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances.

(d) The wholesale distributor must maintain a list of officers, directors, facility managers, designated representatives, and other key personnel in charge of wholesale distribution, including storage and handling, and include a description of their duties and a summary of their qualifications. This list must be available for review by the State or Federal licensing authority.

(e) The wholesale distributor must establish and implement written policies and procedures designed to ensure that the qualifications of key personnel as required in this section are met, maintained, and documented. These written policies and procedures must be available for review by the State or Federal licensing authority, as provided in § 205.27. These policies and procedures must identify the personnel at the wholesale distributor's facility who are responsible for the following actions:

(1) Implementing and maintaining all facility and personnel requirements;

(2) Ensuring that the facility complies with all licensure and reporting requirements; and

(3) Ensuring that key personnel receive initial and regular training to ensure competence relevant to their job functions.

(f) In addition to the qualifications for key personnel in paragraphs (a) through (e) of this section, a facility manager or designated representative must have the following qualifications to carry out those responsibilities:

(1) Serves as the facility manager or designated representative of such facility manager for only one facility at any one time;

(2) Is actively involved in and responsible for managing the daily operations of the wholesale distributor facility; and

(3) Remains responsible for all facility manager or designated representative duties that are delegated to other personnel at the facility.

(g) Any facility manager or designated representative, prior to their association, employment, or contracting with the wholesale distributor as a facility manager or designated representative, must submit a full set of fingerprints for purposes of conducting local and national criminal background checks. The results of the background checks must demonstrate no history of criminal convictions pursuant to paragraph (a) of this section.

§ 205.26 National standards for the storage and handling of prescription drugs for wholesale distribution.

Any facility owned, rented, or leased by a wholesale distributor for engaging in wholesale distribution must meet the facility requirements in paragraphs (a) and (b) of this section, and the wholesale distributor must establish, maintain, and follow policies and procedures as set forth in paragraph (c) of this section.

(a) A wholesale distributor to which a license has been issued in the same name and at the same address as another authorized trading partner, such as a 3PL, must maintain separate systems and processes for the distribution of drugs that are specific to the wholesale distributor.

(b) The facility the wholesale distributor owns, leases, or rents for purposes of engaging in wholesale distribution must be suitable for the storage and handling of prescription drugs, as demonstrated by the following:

(1) *General requirements.* The facility is:

(i) Not a personal residence;

(ii) Of a suitable size, construction, and configuration designed to ensure proper distribution, including storage and handing, of all prescription drugs stored at or distributed from the facility;

(iii) Of a suitable size, construction, and configuration to facilitate cleaning, maintenance, and proper wholesale distribution operations;

(iv) Maintained in a clean and orderly condition, free from infestation of any kind;

(v) Equipped with sufficient lighting, ventilation, temperature, sanitation, humidity, space, equipment, and secure conditions for prescription drug storage; and

(vi) Equipped with clearly defined designated areas that separate saleable prescription drugs from prescription drugs that are unfit for distribution.

(2) *Security of premises.* The facility must be equipped with adequate security to prevent breaches. Adequate security includes ensuring that:

(i) The facility is secure from unauthorized entry;

(ii) Access from outside the premises is limited, well controlled, and documented;

(iii) The outside perimeter of the premises is well lit;

(iv) Entry into areas where prescription drugs are held is limited to key personnel who possess appropriate and verifiable experience and training necessary to safely and lawfully engage in the distribution of prescription drugs, as described in § 205.25, and to staff for purposes of maintenance and cleaning; and

(v) The facility is equipped with a security system that protects against theft and diversion of prescription drugs and accidental or unsanctioned modifications to data, including an alarm system to detect and notify appropriate personnel of any unauthorized entry.

(3) *Equipment.* The facility must have equipment that ensures prescription drugs are properly stored, including cold storage, refrigerators, temperature and humidity devices, and air handling units. All equipment utilized must be maintained in good repair and must be suitable for the distribution, including receipt, storing, and handling, warehousing, holding, displaying, or transporting of prescription drugs, as demonstrated by the following:

(i) All equipment must be installed, maintained, and repaired by qualified individuals following written procedures established by the wholesale distributor. The wholesale distributor must be able to demonstrate that all equipment has been calibrated, as applicable, and validated at regular intervals to achieve the intended results accurately, consistently, and in a manner that can be reproduced by qualified individuals following the wholesale distributor's written procedures. Such actions must be documented;

(ii) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or logs must be used to document proper storage of prescription drugs; and

(iii) Monitoring equipment must immediately alert appropriate personnel of any deviations from the required storage conditions.

(4) *Facility assessments.* Facility assessments, including temperature mapping and other assessments designed to ensure prescription drugs are properly stored in accordance with their labeling, must be regularly conducted and documented.

(c) Every wholesale distributor must establish, maintain, and follow written policies and procedures for each of the requirements described in this section that are relevant to the scope of the wholesale distributor's activities involving prescription drugs at the facility. The written policies and procedures must describe a system by which the wholesale distributor will monitor all processes, and, if deviations occur, promptly document and investigate to determine the root cause of the deviation. If a wholesale distributor uses a contractor to carry out any of its duties, the wholesale distributor remains responsible for compliance with this subpart and must ensure that the contractor abides by the applicable written policies and procedures. The written policies and procedures must clearly describe the responsibilities of the wholesale distributor and any contractors used to fulfill the wholesale distributor's duties. Such arrangements must be documented and carried out in accordance with the requirements of this section.

(1) *Authorized trading partners.* The wholesale distributor must ensure that it conducts business only with other authorized trading partners as defined in section 581(2) and (23) of the Federal Food, Drug, and Cosmetic Act.

(2) *Facility and equipment maintenance management.* The wholesale distributor must ensure that the facility requirements in paragraph (b) of this section are met.

(3) *Transportation.* The wholesale distributor must ensure prescription drugs are transported in a manner that:

(i) Protects against breakage, contamination, adulteration, and theft;

(ii) Prevents exposure to conditions that may compromise prescription drug identity, strength, quality, or purity; and

(iii) Ensures that deviations from storage requirements during transport are identified, investigated, documented, corrected, and reported no later than 24 hours after discovery to the authorized trading partner from which the prescription drug was received, and to the manufacturer to determine if further commercial distribution is appropriate.

(4) *Examination of shipping containers.* The wholesale distributor must ensure that all shipping containers are examined in accordance with the following standards:

(i) *Incoming shipments.* Upon receipt, each shipping container must be visually examined for identity and to prevent the acceptance of prescription drugs that are unfit for distribution. This examination must be adequate to detect conditions that would suggest that the prescription drug may be unfit for distribution, such as alterations made or damage to the shipping container.

(ii) *Outgoing shipments.* Each outgoing shipment must be properly inspected for identity of the prescription drug to ensure that there is no shipment of a prescription drug that has been damaged in storage or held under improper conditions and to prevent the introduction or further shipment of any prescription drug that is unfit for distribution, including through the wholesale distributor's processing of returned or recalled drugs.

(5) *Storage and handling.* The wholesale distributor must ensure that prescription drugs are stored at appropriate temperatures and under appropriate conditions in accordance with the drugs' labeling, except that if no storage requirements are established in the drug's labeling, the drug may be held at controlled room temperature to preserve the drug's identity, strength, quality, and purity.

(i) *Inventory management.* The wholesale distributor must:

(A) Ensure compliance with the requirements of section 582(c) of the Federal Food, Drug, and Cosmetic Act;

(B) Ensure that the facility's stock is inspected regularly to protect against drug diversion and distribution of prescription drugs that are unfit for distribution;

(C) Investigate, document, and correct any stock irregularities, including theft, loss, or diversion of prescription drugs, in accordance with section 582(c) of the Federal Food, Drug, and Cosmetic Act, as applicable;

(D) Ensure that any prescription drug that appears to be unfit for distribution

is removed from saleable stock and handled appropriately according to the requirements in paragraphs (c)(5)(ii) through (iv) of this section;

(E) Immediately report any confirmed losses or theft of prescription drugs to the manufacturer of the drug and the Food and Drug Administration; and

(F) Ensure that records related to the actions required in paragraphs (c)(5)(i) through (iv) of this section are kept according to § 205.27.

(ii) *Handling of prescription drugs.* The wholesale distributor must ensure that only prescription drugs fit for distribution are further distributed or transferred.

(A) Any prescription drug that appears to be unfit for distribution must be stored in a secure area clearly defined for such use and physically segregated from saleable drugs, or electronically segregated, if appropriate, until the wholesale distributor determines by thorough examination that such drugs are fit for human use or nonsaleable.

(B) Any prescription drug found to be adulterated, misbranded, or otherwise unfit for distribution must be stored in a secure area clearly defined for such use and physically or electronically segregated from saleable drugs until they are returned to the supplier or destroyed in accordance with the standards in paragraph (c)(6) of this section.

(C) If a prescription drug is determined to be a suspect or illegitimate product, those suspect or illegitimate products must be handled according to the requirements of section 582(c)(4) of the Federal Food, Drug, and Cosmetic Act.

(iii) *Returned prescription drugs.* All returned prescription drugs must be stored in a secure area clearly defined for such use and physically segregated from saleable prescription drugs, until the wholesale distributor determines by thorough examination that such drugs are saleable or nonsaleable.

(A) *Saleable returns.* Prescription drugs may be returned to saleable stock only if the conditions under which the drug has been returned do not cast doubt on the drug's safety, identity, strength, quality, or purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped.

(B) *Nonsaleable returns.* If the conditions under which the prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, drugs may be returned to the manufacturer or repackager, to the wholesale distributor from which such drug was purchased, or to an individual acting on behalf of such an entity, including a returns processor, or may be destroyed in a timely manner and in accordance with paragraph (c)(6) of this section and all applicable Federal and State laws.

(iv) *Recalled drugs.* Recalled prescription drugs must be handled as instructed by the manufacturer in the recall notice, which may require that the recalled drugs be stored in a secure area clearly defined for such purpose and physically segregated from saleable drugs until they are returned to the manufacturer or repackager, to the wholesale distributor from which such drug was purchased, or to an individual acting on behalf of such an entity, including a returns processor, or destroyed in accordance with the standards in paragraph (c)(6) of this section.

(6) *Disposition of drugs.* The wholesale distributor must establish, maintain, and follow written policies and procedures that ensure that prescription drugs removed from the pharmaceutical distribution supply chain because they are determined to be unfit for distribution are retained for further examination, returned to the manufacturer or repackager, returned to the wholesale distributor from which such drug was purchased, or returned to an individual acting on behalf of such an entity, including a returns processor, or destroyed in accordance with all applicable Federal and State laws and the following standards:

(i) *Quarantine and transfer for further examination.* The wholesale distributor must establish and maintain records for prescription drugs retained in quarantine and subsequently transferred to a manufacturer or regulatory or law enforcement agency for further additional physical examination or laboratory analysis.

(ii) *Return the drugs.* The wholesale distributor must establish and maintain records for the return of prescription drugs to the manufacturer, repackager, or wholesale distributor from which the wholesale distributor acquired the drugs, including when returned using a returns processor or reverse logistics provider to return the drugs.

(iii) *Destroy.* When prescription drugs are authorized for destruction, the wholesale distributor must:

(A) Destroy all containers, labels, and packaging to ensure that such items cannot be used in counterfeiting activities;

(B) Ensure that the destruction of prescription drugs, containers, labels, and packaging are witnessed; and

(C) Establish and maintain records for destroyed drugs and the witnessing thereof.

(7) *Preparation for foreseeable crises.* The wholesale distributor must prepare for, protect against, and address any reasonably foreseeable crises that could affect security or operation of the facility such as strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

§ 205.27 Standards for the establishment and maintenance of records of the distribution of prescription drugs.

(a) *Required records.* Required records include, but are not limited to, the following:

(1) Documentation pertaining to distribution, including storage and handling, security, inventory, transport, and shipping of prescription drugs, including written policies and procedures for identifying, recording, and reporting confirmed losses, thefts, and diversions, and prescription drugs that are unfit for distribution;

(2) All policies, procedures, instructions, contracts, data, inspection reports, and any documentation related to compliance with this subpart; and

(3) Invoices, purchase orders, packing slips, shipping records, and any other records of the distribution of prescription drugs.

(b) *Maintenance, availability, and accuracy of records.* Records must:

(1) Accurately reflect the name of the wholesale distributor as it appears on the wholesale distributor license and must match the information that is reported to the Food and Drug Administration pursuant to the Food and Drug Administration reporting requirements at § 205.29;

(2) Be readily retrievable and made available to regulatory authorities upon request;

(3) Be securely stored and protected from unauthorized access or modifications; and

(4) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.

(c) *Written policies and procedures.* Written policies and procedures must be implemented by the wholesale distributor to protect the integrity of records.

(d) *Record retention.* (1) Except for the records listed in paragraph (d)(2) of this section, all records required to be maintained by this subpart must be retained for a period of 3 years.

(2) Records of investigation of suspect and illegitimate products and of destroyed, nonsaleable returned, and recalled prescription drugs must be retained for a period of 6 years.

§ 205.28 Inspections.

(a) A facility to be used in wholesale distribution must undergo a physical inspection prior to issuance of the initial license by the Federal or State licensing authority.

(1) Where the State is the licensing authority, such inspection may be conducted by:

(i) The State in which the facility to be licensed is located; or

(ii) A third-party accreditation or inspection service approved by the State licensing the wholesale distributor; or

(iii) If the facility is located out of State, the State issuing the license may conduct the inspection or may accept an inspection by the State in which the facility is located or by a third party, as described in paragraph (a)(1)(ii) of this section.

(2) Where the Food and Drug Administration is the licensing authority, the Food and Drug Administration may conduct the inspection or may accept an inspection conducted by an organization approved by the Food and Drug Administration under § 205.32.

(b) Records described in § 205.27 that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within 2 business days of a request by a State or Federal official, or sooner if necessitated by the duration of the inspection.

(c) Wholesale distributors must permit the appropriate Federal, or State licensing authority and State- or FDA-approved third-party inspection services to enter and inspect their premises and to audit their records and written operating procedures.

(d) To ensure compliance with this subpart, routine inspections will be conducted once every 3 years by the licensing authority, or a third-party accreditation or inspection service approved by the Food and Drug Administration or the State licensing the wholesale distributor.

§ 205.29 Requirements for initial and annual reporting to the Food and Drug Administration.

(a) *Electronic reporting requirement.* The wholesale distributor must report electronically to the Food and Drug Administration using a secure mechanism in a format the Food and Drug Administration can review, process, and archive pursuant to section 503(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Information reported will be included in the Food and Drug Administration's public database for wholesale distributors pursuant to section 503(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

(b) *Reporting periods*—(1) *Initial reporting.* Any entity that owns or operates an establishment that engages in wholesale distribution must report within 30 calendar days of obtaining an initial State or Federal wholesale distributor license.

(2) *Annual reporting.* Any entity that is licensed to engage in wholesale distribution must report to the Food and Drug Administration each calendar year between January 1 and March 31.

(c) *Required information.* Information to be reported for each wholesale distributor must include:

(1) A complete list of States where the wholesale distributor is licensed, including the corresponding identification number and the expiration date of each such license;

(2) Name of company as it appears on the license, full business address, and contact information for the facility manager or designated representative of the wholesale distributor;

(3) All trade names or business names under which the wholesale distributor conducts business; and

(4) Any significant disciplinary actions by any State or Federal Agency taken against the wholesale distributor license related to the distribution of prescription drugs, including the State where the disciplinary action occurred, date of final action, type of disciplinary action, description of the violation, and documents associated with the disciplinary action.

(d) *Timing of significant disciplinary action reporting*—(1) *Initial reporting.* The wholesale distributor must report to the Food and Drug Administration any significant disciplinary actions, including but not limited to revocation or suspension of a wholesale distributor license by a State or Federal licensing authority, which occurred in the 12 months prior to obtaining licensure.

(2) *Subsequent reporting.* The wholesale distributor must, within 30 calendar days after a final action taken by a State or Federal licensing authority, report significant disciplinary actions to the Food and Drug Administration.

(e) *Other reports*—(1) *Closure of a facility.* The wholesale distributor must report to the Food and Drug Administration that a facility has ceased operations within 30 calendar days after it has stopped operating as a wholesale distributor.

(2) *Voluntary withdrawal of a State license.* The wholesale distributor must report to the Food and Drug Administration that it has withdrawn its license in a State within 30 calendar days after such withdrawal, including any reasons for the voluntary withdrawal of licensure.

§ 205.30 Licensure denial, suspension, reinstatement, revocation, and voluntary termination—notice and opportunity to request a hearing.

(a) *Denial of application for licensure.* (1) The licensing authority will refuse to approve a wholesale distributor license application for any of the following reasons:

(i) The methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, are inadequate to preserve its safety, identity, strength, quality, or purity.

(ii) The facilities and controls used for the distribution of the prescription drug, including receipt, storage, and handling, are inadequate to preserve its safety, identity, strength, quality, or purity.

(iii) The methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, do not comply with the requirements for good storage practices in § 205.26.

(iv) The personnel employed by the applicant do not meet the requirements necessary for good storage practices in § 205.25.

(v) There is insufficient information in the written policies and procedures required under § 205.26(c) to determine whether the methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, comply with the requirements for good storage practices in § 205.26 and preserve the safety, identity, strength, quality, or purity of the prescription drug.

(vi) The methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, do not comply with the requirements for adequate recordkeeping in § 205.27.

(vii) The application contains an untrue statement of material fact.

(viii) The applicant does not permit a properly authorized officer or employee of the Food and Drug Administration, a State licensing authority, or an AO approved by the Food and Drug Administration pursuant to § 205.32 an adequate opportunity to inspect the

facilities, controls, and any records relevant to the application.

(ix) For renewal applications, the applicant fails to report to the licensing authority any pertinent change of information required in § 205.21, § 205.22, or § 205.24.

(x) For renewal applications, the applicant fails to report to the Food and Drug Administration any of the requirements for annual reporting in § 205.29.

(2) If review of a wholesale distributor's application fails to demonstrate that the wholesale distributor meets the requirements for licensure set forth in § 205.22 and paragraph (a)(1) of this section, the licensing authority will provide written notice to the applicant that its license application may be denied, setting forth the grounds for the denial and providing an opportunity to demonstrate that the wholesale distributor meets the requirements for licensure.

(3) The notice will inform the applicant of its right to provide additional information and request reconsideration of the denial by the licensing authority within 14 calendar days of the date of the licensing authority's written notice.

(4) If no reconsideration is sought, or, if upon reconsideration, the licensing authority denies the applicant's request for licensure, the licensing authority will provide the applicant written notice of the denial and will provide the applicant notice of the opportunity to request a hearing.

(5) The applicant who wishes to request a hearing has 10 calendar days after the date of the notice of denial to submit a written notice of participation and request for a hearing. The applicant who fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(6) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(b) *Suspension of license after notice and opportunity to request a hearing.* (1) The licensing authority may move to suspend a license if the licensing authority has a reasonable belief that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would likely compromise the quality of product or threaten public safety.

(2) The licensing authority will provide written notice of the intent to suspend a wholesale distributor license setting forth the grounds for the suspension pursuant to this part, including what information would be required to demonstrate or achieve compliance. The notice will inform the applicant of its right to provide additional information, request reconsideration of the suspension by the licensing authority, and demonstrate or achieve compliance before suspension.

(3) Each wholesale distributor license holder has 30 calendar days from the date of the notice of intent to suspend to present, in writing, comments and information bearing on the initial decision.

(4) If no comments or information is received within 30 calendar days or, if upon reconsideration, the licensing authority believes the wholesale distributor license should still be suspended, the licensing authority will provide the wholesale distributor a second written notice of the intent to suspend, informing the wholesale distributor of the opportunity to request a hearing on the question of whether there are grounds for suspension.

(5) The wholesale distributor must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of the notice of the intent to suspend. A wholesale distributor that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(6) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(7) If a wholesale distributor's license is suspended and the wholesale distributor does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the wholesale distributor's license.

(c) *Immediate suspension of license.* (1) The licensing authority may suspend a license effective immediately if the licensing authority reasonably believes that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would reasonably be expected to cause an imminent threat to public health.

(2) The licensing authority will provide the wholesale distributor with written notice of immediate suspension of its license setting forth the grounds for the suspension pursuant to this part, including what information would be required to demonstrate compliance, and the opportunity to request a hearing within 10 calendar days of the wholesale distributor's request for such hearing.

(3) The wholesale distributor must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of the written notice of immediate suspension. A wholesale distributor that fails to submit a written notice of participation and request for hearing within 10 calendar days from the date of the written notice waives the opportunity for a hearing.

(4) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(5) If a wholesale distributor's license is suspended and the wholesale distributor does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the wholesale distributor's license.

(d) *Reinstatement of suspended licenses.* The licensing authority may reinstate a previously suspended license upon a wholesale distributor's showing of compliance with requirements in this part and upon such inspection and examination as the licensing authority may require.

(e) *Revocation.* (1) If compliance is not demonstrated or achieved to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the wholesale distributor's license.

(2) The licensing authority will notify the wholesale distributor of the intent to revoke the wholesale distributor's license, setting forth the grounds for the revocation and offering an opportunity to request a hearing on the proposed revocation.

(3) The wholesale distributor must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. A wholesale distributor that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(4) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e)

and 583 of the Federal Food, Drug, and Cosmetic Act.

(f) *Nonrenewal.* If a license renewal application is not submitted by the date of expiration of the license, the license will be considered expired. A wholesale distributor may not engage in wholesale distribution with an expired license and must submit a new application for licensure.

(g) *Voluntary termination of licensure upon request by the wholesale distributor.* The licensing authority will terminate a wholesale distributor's license upon the wholesale distributor's request, which will include a notice of intent to discontinue prescription drug wholesale distribution and waive opportunity for a hearing. A wholesale distributor that voluntarily terminates licensure must obtain a new license before resuming wholesale distribution.

(1) If a wholesale distributor that has had its license revoked wishes to apply for a new license, the wholesale distributor must submit a new license application, which may include an inspection if required by the licensing authority under § 205.28(a).

(2) [Reserved]

Subpart D—Approved Organizations for Wholesale Distributors

§ 205.31 Use of approved third-party organizations.

(a) A third-party organization that has been approved by the Food and Drug Administration pursuant to § 205.32 (''approved organization'' (AO)) may be used to conduct initial and routine inspections of the wholesale distributor's facility, as directed by the Food and Drug Administration.

(b) If an organization has been approved by the Food and Drug Administration to conduct inspections, the AO must:

(1) Complete inspections within a timeframe not to exceed 90 calendar days after receiving notice from the Food and Drug Administration to conduct an inspection;

(2) Based on the inspection, write a detailed document including a summary of the AO's findings; and

(3) Send the original document to the Food and Drug Administration, with a copy to the wholesale distributor, within 7 calendar days of completing the inspection.

(c) To become an AO, and to maintain its approval, an organization seeking the Food and Drug Administration's approval and current AOs must:

(1) Maintain records, including those that support the AO's initial and continuing qualifications for approval, for a minimum of 5 years.

(2) Maintain the following records of inspections submitted to the licensing authority for a minimum of 5 years:

(i) Copies of the records and supporting documentation reviewed as part of an inspection;

(ii) Inspection reports;

(iii) Correspondence with the Food and Drug Administration and the wholesale distributor associated with an inspection; and

(iv) Information on the identity, conflict of interest certification/compliance statement, and qualifications of all AO personnel who contributed to the inspection.

(3) Records maintained by the AO must:

(i) Be readily retrievable and made available to Federal licensing authorities upon request;

(ii) Be secure from unauthorized access or modifications; and

(iii) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.

(4) An AO must immediately report to the Food and Drug Administration the discovery of any evidence or observations of potential violations found at a wholesale distributor facility during an inspection of the facility that could pose imminent and serious adverse health consequences or death to humans. Reports must be made in the manner prescribed by the Food and Drug Administration.

§ 205.32 General qualifications of approved organizations.

(a) To become and remain an AO, the organization and anyone employed by the organization, including contractors used by the organization:

(1) Must not be a current Federal or State government employee;

(2) Must not engage in prescription drug-related activities, excluding participation in the Agency's AO program and related activities, but including and not limited to manufacturing, wholesale distribution, repackaging, relabeling, dispensing, or 3PL activities;

(3) Must disclose to the Food and Drug Administration any participation or financial interest in entities that participate in the design, manufacture, promotion, or sale of articles or activities that are predominantly Food and Drug Administration-regulated or are expected to result in Food and Drug Administration-regulated articles;

(4) Must not be owned or controlled by, or have any organizational, material, or financial affiliation with, any of the entities engaged in manufacturing, wholesale distribution, repackaging, relabeling, dispensing, 3PL activities, or the design, manufacture, promotion, or sale of prescription drugs as defined in section 581(12) of the Federal Food, Drug, and Cosmetic Act;

(5) Must enter and abide by a written agreement with the applicant before data and information otherwise exempt from public disclosure may be disclosed to the AO or the contractor;

(6) Must operate in accordance with professional and ethical business practices, which include:

(i) Protecting against conflicts of interest as set forth in 5 CFR part 2635 and 18 U.S.C. 208;

(ii) Ensuring that the personnel employed or contracted by the AO who are working on inspections have sufficient education, training, knowledge, and experience to conduct inspections of wholesale distributors;

(iii) Protecting against unauthorized disclosure of nonpublic information received, records, reports, and recommendations and maintaining appropriate security and protection of such information;

(iv) Maintaining appropriate security and protection, physical and electronic, of any information received in relation to inspections;

(v) Reporting information to the Food and Drug Administration and entities for which licensure reviews were conducted that accurately reflects data reviewed, inspectional observations made, and other matters that relate to or may influence compliance with the Federal Food, Drug, and Cosmetic Act; and

(vi) Promptly responding to and attempting to resolve any complaints regarding activities for which it is approved by the Food and Drug Administration; and

(7) Must establish and maintain policies, procedures, and documentation to demonstrate that, at the time of application, and throughout their tenure as an AO, the applicant has and can continue to satisfy the requirements to qualify as an AO capable of assessing compliance with all wholesale distributor requirements. Such policies, procedures, and documentation must include, but are not limited to:

(i) AO program administration;

(ii) Disciplinary actions and corrective measures;

(iii) Recordkeeping and confidentiality;

(iv) Use of contractors; and

(v) Personnel qualifications and ongoing training.

(b) If an AO elects to use contractors for inspections, the AO remains

responsible for the work of the contractors at all times.

(1) AOs that use contractors to conduct inspections must have policies and procedures in place to ensure the contractor's continuing compliance with this part, as well as competence and qualifications to conduct inspections. Such policies and procedures must ensure that contractors:

(i) Meet the qualifications set forth in paragraph (a) of this section;

(ii) Do not subcontract their inspection duties, and that contractors are removed if such requirement is violated;

(iii) Abide by the policies and procedures of the AO, as set forth in § 205.33(b); and

(iv) Complete and pass the same training required by the AO, as set forth in § 205.33(c).

(2) If an AO elects to use contractors to conduct inspections, the AO must receive and keep a record of written consent from the wholesale distributor to share confidential commercial information with contractors for which an inspection is being conducted.

(3) AOs that elect to use contractors must submit to the Food and Drug Administration a list of contractors used by the organization, accompanied by a statement from the organization certifying that such contractors meet the requirements of this subpart.

§ 205.33 Process and procedures for approval by the Food and Drug Administration.

(a) *Application.* An application to become an AO must be completed and submitted electronically to the Food and Drug Administration in a format the Food and Drug Administration can renew, process, and archive.

(b) *Required application information.* Policies, procedures, and documentation as required by § 205.32(a)(7) must accompany the application.

(c) *Training.* Organizations must provide training and any individual who conducts inspections or supervises individuals who conduct inspections is required to undergo and pass the prescribed training.

(1) If an individual does not pass training, that person must wait 30 days before retaking the training, and may be required to show proof of additional education or experiential learning to demonstrate competence before retaking the training evaluation.

(2) To maintain approval, individuals employed by the AO and conducting inspections or supervising those who conduct inspections must undergo and pass annual training as prescribed by the Food and Drug Administration. Failure to complete and pass annual training may result in suspension of approval.

(3) The Food and Drug Administration may require additional training. If such additional training is required, AOs will be given a set time period during which training must be completed and passed to maintain approval.

(d) *Auditing.* Prior to conducting its first inspection, an AO must undergo an onsite audit by the Food and Drug Administration. The Food and Drug Administration may also conduct random, periodic audits, as well as for-cause audits, of an AO, as set forth in paragraph (o) of this section.

(e) *Duration of approval and renewal process.* (1) The Food and Drug Administration approval to conduct inspections is valid for a period of 5 years.

(2) AOs must submit a renewal application to the Food and Drug Administration no later than 6 months prior to the expiration date to renew its approval.

(i) If a renewal application is submitted less than 6 months before the date of expiration, the AO's approval will expire if approval is not renewed prior to the date of expiration.

(ii) Upon expiration of the AO's approval, the AO must cease conducting any inspection-related activities.

(f) *Denial of approval.* If an organization does not meet all of the Food and Drug Administration's standards detailed in §§ 205.31 and 205.32 for becoming an AO, the Food and Drug Administration will deny the application in writing. Requests for review and reconsideration of a denial of an application must be submitted to the Food and Drug Administration within 30 calendar days of the date of the Food and Drug Administration's decision. If, upon reconsideration, the licensing authority denies the applicant's request for approval, the licensing authority will provide the applicant written notice of the denial and an opportunity to appeal pursuant to § 10.75 of this chapter.

(g) *Suspension of approval after notice and opportunity to request a hearing.* (1) The Food and Drug Administration may suspend approval of an organization after opportunity to request a hearing when there is a reasonable probability that the organization's noncompliance will negatively impact public health.

(2) If an AO fails to maintain the Food and Drug Administration's standards pursuant to §§ 205.31 and 205.32, the Food and Drug Administration will give written notice of the intent to suspend the organization's approval, including the grounds for the suspension, and the AO will have 30 days after the date of the notice to provide additional information to the Food and Drug Administration for reconsideration.

(3) If no additional information is provided or, if upon reconsideration, the Food and Drug Administration still believes the AO's approval should be suspended, the Food and Drug Administration will issue the AO a formal written notice of intent to suspend, along with notice of the opportunity to request a hearing pursuant to part 16 of this chapter.

(4) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of intent to suspend to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days from the date of the notice waives the opportunity for a hearing.

(5) A suspended AO must notify any wholesale distributors with a pending inspection to be performed by the AO of the AO's suspension within 7 calendar days.

(h) *Immediate suspension of approval.* (1) When there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans, the Food and Drug Administration will suspend an AO's approval effective immediately.

(2) In such a situation, the Food and Drug Administration will provide the AO a written notice of immediate suspension, along with notice and opportunity to request a hearing pursuant to part 16 of this chapter within 14 calendar days of the AO's request for such hearing.

(3) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of suspension to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(i) *Reinstatement of approval.* (1) An organization's approval may be reinstated if the Food and Drug Administration determines that the suspended organization has rectified the issues leading to the suspension and can meet the standards set forth in this subpart. Pursuant to this paragraph (i), the organization must rectify the issues and come into compliance with the Food and Drug Administration's

standards within 1 year from the date of suspension. If the issues have not been rectified within 1 year, the Food and Drug Administration may revoke the AO's approval subject to the provisions of this part.

(2) An organization whose approval has been reinstated on a conditional basis will be subject to a 3-year probationary period, and if any material deficiencies arise during that period, the organization's approval may be revoked.

(j) *Revocation of approval.* (1) The Food and Drug Administration may revoke approval of an organization whose approval has been suspended pursuant to paragraphs (g) and (h) of this section:

(i) If an organization fails to demonstrate intent to comply with the issues leading to the suspension within 6 months from the date of suspension; or

(ii) If the Food and Drug Administration determines that the organization failed to rectify the issues leading to the suspension to the Agency's satisfaction within 1 year of the date of suspension.

(2) The Food and Drug Administration will give written notice of the intent to revoke the organization's approval, including the grounds for the revocation, and an opportunity to request a hearing pursuant to part 16 of this chapter.

(3) The AO must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. An AO that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(4) An organization whose approval is revoked that wishes to reapply to be an AO must submit a new application to the Food and Drug Administration.

(k) *Requests for reconsideration of Agency decision.* (1) The Food and Drug Administration will follow the process outlined at § 10.75 of this chapter to review matters relating to denial of approval, including review of the organization's application.

(2) The Food and Drug Administration will follow the process outlined at part 16 of this chapter to review matters relating to a suspension or revocation action, including review of the organization's application and administrative file.

(3) The Food and Drug Administration's decision after request for reconsideration of denial, suspension, or revocation constitutes a final Agency action under 5 U.S.C. 702.

(l) *Voluntary withdrawal of approval.* (1) An organization wishing to voluntarily withdraw its approval, including but not limited to when an AO goes out of business, must notify the Food and Drug Administration in writing at least 6 months prior to the date the organization intends for the withdrawal to become effective.

(i) If an AO determines it will be withdrawing its approval with the Food and Drug Administration in less than 6 months, it must notify the Food and Drug Administration immediately of its intent to withdraw, and such notification must inform the Food and Drug Administration of the date the organization will cease business operations.

(ii) [Reserved]

(2) No later than 7 calendar days after notifying the Food and Drug Administration, the organization must notify any facilities with pending inspections that it intends to withdraw its approval with the Food and Drug Administration and must provide the date on which the withdrawal is effective.

(m) *AO-required notifications to wholesale distributors.* The AO must, within 7 calendar days of the date of suspension, revocation, or voluntary withdrawal of approval, notify those wholesale distributor facilities that have pending inspections of the AO's suspension or revocation. This notification must inform the wholesale distributor facility that it must apply for inspection with another AO, or the Food and Drug Administration if no other organization is approved.

(n) *Change of operation or ownership.* (1) The AO must report to the Food and Drug Administration within 30 calendar days any changes to the information submitted with its application for approval.

(2) Approval is not transferable.

(i) Changes in ownership of an AO require the organization to submit a new application to the Food and Drug Administration.

(ii) Such application must be submitted to the Food and Drug Administration no later than 30 calendar days prior to the date of the change of ownership.

(iii) No later than 30 calendar days before the date of the change of ownership, the AO must notify any wholesale distributor facilities with pending applications of the pending change in ownership.

(iv) On the date the change of ownership takes place, the original approval is void.

(o) *Monitoring by the Food and Drug Administration.* (1) AOs are subject to both periodic and for-cause audits by the Food and Drug Administration to ensure compliance with the Food and Drug Administration's requirements for approval in this part.

(2) If an AO refuses to cooperate with the Food and Drug Administration's audit, the organization's approval may be suspended.

Dated: January 24, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

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