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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0644; Product Identifier 2019–CE–057–AD; Amendment 39–21160; AD 2020–14–06]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Diamond Aircraft Industries Models DA 40, DA 40 F, and DA 40 NG airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as deterioration of the fuel tank connection hoses that could result in restriction of fuel flow leading to fuel starvation and reduced control of the airplane. The FAA is issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective August 4, 2020.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of August 4, 2020.

The FAA must receive comments on this AD by August 31, 2020.

ADDRESSES: You may send comments by any of the following methods:

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

For service information identified in this AD, contact Customer Support, Diamond Aircraft Industries, Inc., 1560 Crumlin Sideroad, London, Ontario, Canada, N5V 1S2; Phone: (519) 457–4041, Fax: (519) 457–4045; Email: *support-canada@diamondaircraft.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0644.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0644; 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 AD, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Joseph Catanzaro, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 287–7366; fax: (516) 794–5531; email: *joseph.catanzaro@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

Transport Canada, which is the aviation authority for Canada, has issued AD No. CF–2019–39, dated October 31, 2019 (referred to after this as ''the MCAI''), to correct an unsafe condition for Diamond Aircraft Industries Models DA 40, DA 40 D, DA 40 F, and DA 40 NG airplanes. The MCAI states:

> Diamond Aircraft Industries (DAI) has received reports of fuel tank connection hose deterioration on the DA 40 aeroplanes. In a number of cases, rubber parts from the hoses were found in the fuel tank and gascolator. Investigation determined that the affected connection hoses originated from two isolated batches. Some of the affected hoses were installed on aeroplanes during production, while others were sold as replacement parts.
>
> Deterioration of fuel tank connection hoses, if not corrected, could result in contamination of the fuel system and restriction of fuel flow, leading to fuel starvation and reduced control of the aeroplane.
>
> To address this unsafe condition, DAI issued Mandatory Service Bulletins (MSBs) to provide instructions for identifying and replacing the affected parts. The MSBs also provide instructions to inspect the fuel tank chambers and remove rubber parts that have detached from the hoses. This AD mandates replacement of the affected parts, associated inspections and corrective actions detailed in the MSBs.

You may examine the MCAI on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0644.

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following Diamond Aircraft Industries Mandatory Service Bulletins: MSB 40–087, Revision 3, dated November 5, 2019, for the Model DA 40 airplanes; MSB F4–037, Revision 3, dated November 5, 2019, for the Model DA 40 F airplanes; and MSB 40NG–064, Revision 2, dated August 29, 2019, for the Model DA 40 NG airplanes. The FAA also reviewed the following Diamond Aircraft Industries Work Instructions: WI–MSB 40–087, Revision 0, dated July 1, 2019, for the Model DA 40 airplanes; WI–MSB F4–037, Revision 0, dated July 1, 2019, for the Model DA 40 F airplanes; and WI–MSB 40NG–064, Revision 0, dated July 1, 2019, for the Model DA 40 NG airplanes. In combination for the applicable model airplane, the service bulletins and work instructions contain procedures for identifying and replacing affected parts, inspecting the fuel tank chambers, and removing rubber material that has detached from the hoses. This service information is reasonably available because the interested parties have access to it through their normal

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

FAA's Determination and Requirements of the AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this AD because the FAA evaluated all information provided by the State of Design Authority and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because deterioration of fuel tank connection hoses could result in contamination of the fuel system and restriction of fuel flow, resulting in fuel starvation and reduced control of the airplane. Additionally, the compliance time for the required actions is shorter than the time necessary for the public to comment and for publication of the final rule. Therefore, the FAA finds good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reasons stated above, the FAA finds that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and the FAA did not precede it by notice and opportunity for public comment. The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–0644; Product Identifier 2019–CE–057–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this AD. The FAA will consider all comments received by the closing date and may amend this AD because of those comments.

The FAA will post all comments it receives, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact it receives about this AD.

Costs of Compliance

The FAA estimates that this AD will affect 737 products of U.S. registry. The FAA also estimates that it would take about 16 work-hours per product to comply with the requirements of this AD. The average labor rate is $85 per work-hour. Required parts would cost about $48 per product.

Based on these figures, the FAA estimates the cost of the AD on U.S. operators to be $1,408 per airplane, or $1,037,696 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory 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 the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Regulatory Findings

The FAA determined that this proposed 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.

Adoption of 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 (AD):

2020–14–06 Diamond Aircraft Industries Inc.: Amendment 39–21160; Docket No. FAA–2020–0644; Product Identifier 2019–CE–057–AD.

(a) Effective Date

This AD becomes effective August 4, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Diamond Aircraft Industries Inc. Models DA 40, DA 40 F, and DA 40 NG airplanes (including Model DA 40 NG airplanes that have been converted from the Model DA 40 D), all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 28: Fuel System.

(e) Reason

This AD was prompted by deterioration of the fuel tank connection hoses, which if not addressed, could result in contamination of the fuel system and restriction of fuel flow. The FAA is issuing this AD to detect and prevent fuel starvation and reduced control of the airplane.

(f) Actions and Compliance

(1) For purposes of this AD, ''affected part'' means a fuel tank connection hose that meets the criteria in paragraph (f)(1)(i), (ii), or (iii) of this AD.

(i) Part number (P/N) D4D–2817–10–70 installed during production on Model DA 40 NG airplanes with a serial number listed in Section I.2. of Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40NG–064, Revision 2, dated August 29, 2019; or

(ii) P/N D4D–2817–10–70 or BENOLPRESS (no part number) purchased between July 13, 2017, and February 26, 2019, as listed in Section I.11 of Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40–087, Revision 3, dated November 5, 2019;

Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40NG–064, Revision 2, dated August 29, 2019; or Diamond Aircraft Industries Mandatory Service Bulletin No. MSB F4–037, Revision 3, dated November 5, 2019; or

(iii) P/N D4D–2817–10–70 installed as a replacement part on or after July 13, 2017, if it is unknown whether the part meets the criteria in paragraph (f)(1)(i) or (ii) of this AD.

(2) Unless already done, within 100 hours time-in-service (TIS) after August 4, 2020 or within 2 months after August 4, 2020, whichever occurs first, replace each affected part, inspect the main fuel tank chambers, and remove any detached rubber material in accordance with Sections III.1 and III.2 of the Instructions in Diamond Aircraft Industries Work Instruction WI–MSB 40–087, Revision 0, dated July 1, 2019; Diamond Aircraft Industries Work Instruction WI–MSB F4–037, Revision 0, dated July 1, 2019; or Diamond Aircraft Industries Work Instruction WI–MSB 40NG–064, Revision 0, dated July 1, 2019; as applicable to your model airplane, except you are not required to report information to the manufacturer.

(3) As of August 4, 2020, do not install an affected part on any airplane.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send your request to your principal inspector (PI) or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to Joseph Catanzaro, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 287–7366; fax: (516) 794–5531; email: *joseph.catanzaro@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate PI, or lacking a PI, the manager of the local Flight Standards District Office.

(h) Related Information

Refer to Transport Canada AD No. CF–2019–39, dated October 31, 2019. You may examine the Transport Canada AD on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0644.

(i) Material Incorporated by Reference

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

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

(i) Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40–087, Revision 3, dated November 5, 2019.

(ii) Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40NG–064, Revision 2, dated August 29, 2019.

(iii) Diamond Aircraft Industries Mandatory Service Bulletin No. MSB F4–037, Revision 3, dated November 5, 2019.

(iv) Diamond Aircraft Industries Work Instruction WI–MSB 40–087, Revision 0, dated July 1, 2019.

(v) Diamond Aircraft Industries Work Instruction WI–MSB 40NG–064, Revision 0, dated July 1, 2019.

(vi) Diamond Aircraft Industries Work Instruction WI–MSB F4–037, Revision 0, dated July 1, 2019.

(3) For Diamond Aircraft Industries, Inc. service information identified in this AD, contact Customer Support, Diamond Aircraft Industries, Inc., 1560 Crumlin Sideroad, London, Ontario, Canada, N5V 1S2; Phone: (519) 457–4041, Fax: (519) 457–4045; Email: *support-canada@diamondaircraft.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0644.

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

Issued on July 1, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–15133 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0579; Product Identifier 2020–NM–009–AD; Amendment 39–21163; AD 2020–14–09]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company 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 The Boeing Company Model 737–8 and 737–9 (737 MAX) airplanes. This AD requires removing Kathon FP 1.5 biocide from the fuel tanks and engines, installing a fuel limitation placard, and revising the existing airplane flight manual (AFM) to prohibit operation of the airplane with Kathon FP 1.5 biocide in a fuel tank or engine. This AD was prompted by a report indicating that Kathon FP 1.5 biocide added to fuel and running through the engines can lead to significant engine anomalies. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 15, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 15, 2020.

The FAA must receive comments on this AD by August 31, 2020.

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 Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0579.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0579; 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 Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Christopher Baker, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–

231–3552; email: *Christopher.R.Baker@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA has received a report indicating that a Boeing Model 787 airplane equipped with General Electric Company (GE) GEnx–1B model turbofan engines experienced temporary thrust anomalies on both engines during descent into Kansai, Japan, on March 29, 2019. Specifically, both engines briefly fell below idle thrust, and the flightcrew received failure messages for both engines.

The FAA's review of the data from this incident indicated the thrust anomalies resulted from fuel control instability. The fuel tanks of the event airplane had recently been treated with Kathon FP 1.5 biocide for suspected microbial growth contamination. Salt crystals can form in the fuel under certain conditions after Kathon FP 1.5 biocide is applied. These salt crystals have the potential to cause slow response of engine hydromechanical control features, resulting in compressor stalls or flameouts, potentially on both engines.

Having similar fuel system architecture as the GE GEnx engines, the CFM International S.A. (CFM) LEAP–1B model turbofan engines, which are installed on 737 MAX airplanes, are also considered susceptible to a multi-engine loss-of-thrust-control event. This condition, if not addressed, could result in malfunction of the engine's control system hydromechanical unit due to undispersed Kathon FP 1.5 biocide contaminating and restricting the movement of internal parts. Because the fuel systems for both engines on an affected airplane are likely to be similarly affected, there is the potential for loss of thrust control on both engines. Loss of thrust control on both engines could result in failure to climb on takeoff, a forced off-airport landing, or an unacceptably high flightcrew workload.

However, after this biocide is added to the fuel tanks, adding fuel without biocide diminishes the hazard. Eventually, after the tanks have been refilled a sufficient number of times with untreated fuel, enough of the treated fuel is gone that the unsafe condition has been removed. Specifically, Boeing determined that operating the airplane, or any individual engine, for at least 30 flight cycles, while adding only fuel that has not been treated with this biocide, would flush the biocide from the fuel tank system and the engines. The FAA finds this number of flight cycles to be sufficiently conservative, and therefore has incorporated it the requirements of this AD.

The FAA's analysis of the risks posed by this issue has been ongoing, as has the information available to the agency. On March 10, 2020, the manufacturer of Kathon FP 1.5 withdrew that product from the aviation market, effective immediately. A copy of that letter is in the docket for this rulemaking. On March 25, 2020, the FAA issued a Special Airworthiness Information Bulletin (SAIB), which is in the docket for this rulemaking, regarding the effects of Kathon FP 1.5 and another biocide. Most recently, on June 25, 2020, the Japan Transport Safety Board issued an ''Aircraft Serious Incident Investigation Report'' regarding the March 29, 2019 incident. That report is in the docket for this rulemaking.

The FAA may consider similar rulemaking to address the unsafe condition on other airplane models, such as the aforementioned Boeing 787, pending findings from further investigation of other engines.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Multi-Operator Message MOM–MOM–20–0522–01B, dated June 24, 2020, which describes procedures for removing Kathon FP 1.5 biocide from the fuel tanks and engines. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

AD Requirements

This AD requires removing Kathon FP 1.5 biocide from the fuel tanks and engines, installing a fuel limitation placard, and revising the existing AFM to prohibit operation of the airplane with Kathon FP 1.5 biocide in a fuel tank or engine.

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 flightcrews justifies foregoing notice and comment prior to adoption of this rule because the simultaneous loss of thrust control on both engines, due to malfunction of the engine's control system hydromechanical unit due to undispersed Kathon FP 1.5 biocide contaminating and restricting the movement of internal parts, could result in failure to climb on takeoff, a forced off-airport landing, or an unacceptably high flightcrew workload. In addition, the compliance time for the required action is shorter than the time necessary for the public to comment and for publication of the final rule. The FAA acknowledges that it prohibited most operations of airplanes covered by this AD, by emergency order dated March 13, 2019, a copy of which is in the docket for this rulemaking. However, that order allows these airplanes to be operated without carrying passengers, for specific purposes such as repairs, alterations, maintenance, and production flight testing. Therefore this rule must be issued immediately, to ensure the safety of the flightcrews conducting such flights. 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 forgo 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 the **ADDRESSES** section. Include the docket number FAA–2020–0579 and Product Identifier 2020–NM–009–AD at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing

date and may amend this 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 FAA 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 Christopher Baker, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3552; email: *Christopher.R.Baker@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act (RFA)

The requirements of the 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 the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 75 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Kathon FP 1.5 biocide removal.	Up to 24 work-hours × $85 per hour = Up to $2,040	$30	$2,070	Up to $155,250.
Fueling placard installation	2 work-hours × $85 per hour = $170	Minimal	170	12,750.
AFM revision	1 work-hour × $85 per hour = $85	0	85	6,375.

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.

Adoption of 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 (AD):

2020–14–09 The Boeing Company: Amendment 39–21163; Docket No. FAA–2020–0579; Product Identifier 2020–NM–009–AD.

(a) Effective Date

This AD is effective July 15, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 737–8 and 737–9 airplanes with an airworthiness certificate or export certificate of airworthiness issued on or before the effective date of this AD, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 2810, Fuel storage.

(e) Unsafe Condition

This AD was prompted by a report that Kathon FP 1.5 biocide, when used as a fuel additive and running through the engines, can lead to significant engine anomalies. The FAA is issuing this AD to prevent these anomalies, which could result in loss of thrust control on both engines because the fuel systems for both engines are likely to be similarly affected. Loss of thrust control on both engines could result in failure to climb on takeoff, a forced off-airport landing, or an unacceptably high flightcrew workload.

(f) Compliance

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

(g) Removal of Kathon FP 1.5 Biocide

(1) For airplanes identified in paragraphs (g)(1)(i) and (ii) of this AD: Before further flight, remove Kathon FP 1.5 biocide from the fuel tanks and engines, as applicable, in accordance with Boeing Multi-Operator Message MOM–MOM–20–0522–01B, dated June 24, 2020.

(i) Airplanes that have operated for fewer than 30 flight cycles after the last treatment with Kathon FP 1.5 biocide.

(ii) Airplanes having any engine where that engine has operated for fewer than 30 flight cycles after the last exposure to Kathon FP 1.5 biocide.

(2) No action is required by paragraph (g) of this AD for the engines on which CFM confirmed via myCFM case response that the engines are operating as expected.

(h) Fueling Placard Installation

Before further flight, install a placard with letters having a minimum height of 0.20 inch on white or light gray background containing the text ''DO NOT OPERATE ENGINE WITH KATHON™ FP 1.5 BIOCIDE FUEL ADDITIVE'' on the interior area of the refuel access panel in a location that allows refueling personnel full view of the placard text when the access door is open.

(i) AFM Revision for Fuel Additive Limitation

Before further flight, revise the Certificate Limitations section of the existing airplane flight manual (AFM) to include the information specified in figure 1 to paragraph (i) of this AD. This may be done by inserting a copy of this AD into the existing AFM. When a statement identical to that in figure 1 to paragraph (i) of this AD has been included in the general revisions of the existing Boeing 737 AFM, the general revisions may be inserted into the existing AFM, and the copy of this AD may be removed from the existing AFM.

Figure 1 to paragraph (i) – *AFM revision of Certificate Limitations section*

Engines – Fuel system Required by AD 2020-14-09

Operation of the CFM LEAP-1B series engines with fuel containing Kathon FP 1.5 biocide is prohibited.

(j) Special Flight Permit

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed until the actions required by paragraph (g) of this AD have been accomplished.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle 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 (l) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(l) Related Information

For more information about this AD, contact Christopher Baker, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3552; email: *Christopher.R.Baker@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) Boeing Multi-Operator Message MOM–MOM–20–0522–01B, dated June 24, 2020.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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

Issued on July 2, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–15410 Filed 7–13–20; 2:00 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket Nos. RM01–8–000, RM10–12–000, RM12–3–000, ER02–2001–000]

Filing Requirements for Electric Utility Service Agreements; Electricity Market Transparency Provisions of Section 220 of the Federal Power Act; Revisions to Electric Quarterly Report Filing Process; Electric Quarterly Reports

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order Revising and Clarifying Electric Quarterly Report Reporting Requirements.

SUMMARY: The Commission revises its Electric Quarterly Report (EQR) reporting requirements to require time zone information to be reported in connection with transmission capacity reassignments. The Commission declines to adopt proposals to require transmission providers to report ancillary services transaction data in the EQR or to require filers to submit certain information currently submitted into the eTariff system in the EQR. However, the Commission clarifies the information that should be reported in the EQR with respect to ancillary services, including black start service, and tariff-related information. Finally, with respect to booked out transactions, the Commission declines to adopt the proposal to require filers to distinguish between booked out energy and booked out capacity.

DATES: This rule is effective September 14, 2020.

FOR FURTHER INFORMATION CONTACT:

Donald Callow (Technical Information), Office of Enforcement, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8838

Maria Vouras (Legal Information), Office of Enforcement, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8062

SUPPLEMENTARY INFORMATION:

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1. In this order, pursuant to sections 205 and 220 of the Federal Power Act (FPA),[1] we revise and clarify certain Electric Quarterly Report (EQR) reporting requirements and make corresponding updates to the EQR Data Dictionary based on the comments received in response to the proposed rule issued in this proceeding.[2] In particular, we will require filers reporting transmission capacity reassignments to report time zone information in the Contract Data section of the EQR. We decline to adopt the proposed requirements in the Proposed Rule to require transmission providers to report ancillary services transaction data in the EQR or to require the collection of certain tariff-related information in the EQR that is currently submitted into the eTariff system, but we do clarify the information that should be reported in the EQR with respect to ancillary services and tariff-related information. Specifically, with regard to reporting black start service information in the EQR, we clarify that filers should report only seller-level (not unit-specific) information to minimize the possible disclosure of sensitive information. Finally, with respect to booked out transactions, we do not adopt the proposal to require filers to report booked out energy transactions separately from booked out capacity transactions. As discussed further below, Commission staff will discuss reporting of booked out transactions with industry at a future EQR Users Group meeting before the Commission provides further guidance on how to report these transactions in the EQR.

I. Background

2. In Order No. 2001, the Commission amended its filing requirements to require companies subject to Commission regulations under FPA section 205 to electronically file EQRs summarizing the contractual terms and conditions in their agreements for all jurisdictional services, including cost-based sales, market-based rate sales, and transmission service, as well as transaction information for short-term and long-term market-based power sales and cost-based power sales.[3] In Order No. 768, the Commission, among other things, revised the EQR filing requirement to require non-public utilities with more than a *de minimis* market presence to file EQRs, pursuant to FPA section 220.[4]

3. In June 2016, the Commission issued an order implementing certain clarifications to the EQR reporting requirements and updating the EQR Data Dictionary.[5] The June Order clarified reporting requirements related to EQR Data Dictionary Fields, Increment Name and Commencement Date of Contract Terms; affirmed the requirement that transmission providers must report transmission-related data in their EQRs; made certain updates to the EQR Data Dictionary; and clarified that

[1] 16 U.S.C. 824d, 824t.

[2] *Filing Requirements for Elec. Util. Serv. Agreements,* 81 FR 69731 (Oct. 7, 2016), 156 FERC ¶ 61,211 (2016) (Proposed Rule).

[3] *Revised Pub. Util. Filing Requirements,* Order No. 2001, 67 FR 31043 (May 8, 2002), 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, 72 FR 56735 (Oct. 4, 2007), 120 FERC ¶ 61,270, *order on reh'g and clarification,* Order No. 2001–H, 73 FR 1876 (Jan. 10, 2008), 121 FERC ¶ 61,289 (2007), *order revising filing requirements,* Order No. 2001–I, 73 FR 65526 (Nov. 4, 2008), 125 FERC ¶ 61,103 (2008).

[4] *Elec. Mkt. Transparency Provisions of Section 220 of the Federal Power Act,* Order No. 768, 77 FR 61895 (Oct. 11, 2012), 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).

[5] *Filing Requirements for Elec. Util. Serv. Agreements,* 155 FERC ¶ 61,280 (June Order), *order on reh'g and clarification,* 157 FERC ¶ 61,180 (2016) (December Order).

future minor or non-material changes to EQR reporting requirements and the EQR Data Dictionary, such as those outlined in the June Order, will be posted directly to the Commission's website and EQR users will be alerted via email of these changes. The June Order further clarified that significant changes to the EQR reporting requirements and EQR Data Dictionary will be proposed in a Commission order or rulemaking, which would provide an opportunity for comment.[6] On rehearing, the Commission granted clarification with respect to reporting the ''Increment Name'' and the ''Commencement Date of Contract Terms'' and extended the deadline to comply with these clarifications to the Q1 2017 EQR filing.

4. In 2016, the Commission requested comments on proposed revisions and clarifications of certain EQR reporting requirements and corresponding updates to the EQR Data Dictionary.[7] The Commission specifically sought comments on whether to require: (a) Transmission providers to report ancillary services transaction data; (b) filers to submit into the FERC Tariff Reference fields in the EQR certain tariff-related information that they currently submit in the eTariff system; and (c) filers to submit time zone information in connection with transmission capacity reassignment transactions. The Commission also proposed to clarify how booked out transactions should be reported in the EQR. In addition, the Commission explained that, unlike the minor or non-material changes implemented in the June Order, the proposed revisions and clarifications in the Proposed Rule may be more significant for EQR filers to implement.

II. Discussion

5. Bonneville Power Administration (Bonneville), California Independent System Operator Corporation (CAISO), Duke Energy Corporation (Duke), Edison Electric Institute (EEI), Electric Power Supply Association (EPSA), Energy Compliance Consulting, LLC (ECC),[8] Midcontinent Independent System Operator, Inc. (MISO), PJM Interconnection, L.L.C. (PJM), and Southwest Power Pool, Inc. (SPP) filed comments in response to the Proposed Rule.

6. As discussed above, in this order, we adopt only the requirement to report time zone information for transmission capacity reassignments. Filers will be required to do so by April 30, 2021, when the Q1 2021 EQR filings are due. In addition, the revisions to the EQR Data Dictionary adopted in this order are reflected in redline in Attachment A of this order. These revisions must also be applied by April 30, 2021, when the Q1 2021 EQR filings are due.

A. Ancillary Services Transactions

1. Proposed Rule

7. In Order No. 888, the Commission adopted six ancillary services to be included in the open access transmission tariff (OATT).[9] The six ancillary services established in Order No. 888 are offered under the *pro forma* OATT. In Order No. 890, the Commission also adopted Generator Imbalance as a new ancillary service.[10]

8. In Order No. 697, the Commission revised its standards for market-based rate authority for sales of electric energy, capacity, and ancillary services.[11] Among other things, the Commission required third-party sellers of ancillary services at market-based rates to provide information about their ancillary services transactions in the EQR.[12] Following the issuance of Order No. 697, in Order No. 2001–I, the Commission clarified that third-party providers of ancillary services must submit information about their ancillary services associated with unbundled sales of transmission services in the Transaction Data section of the EQR, and that information about ancillary services reported by transmission providers should only be reported in the Contract Data section of the EQR.[13] Accordingly, the Commission revised the EQR Data Dictionary definitions for certain ancillary services-related product names in Appendix A to state: ''For Contracts, reported if the contract provides for sale of the product. For Transactions, sales by third-party providers (*i.e.,* non-transmission function) are reported.'' [14]

9. As stated above, the Commission currently requires transmission providers to report only information about their ancillary services agreements in the Contract Data section of the EQR, while third-party providers of ancillary services must report information about their ancillary services in both the Contract Data and Transaction Data sections of the EQR. In the Proposed Rule, the Commission proposed to require transmission providers to report information about the transactions made under their ancillary services agreements in the Transaction Data section of the EQR. The Commission explained that, without information about their ancillary services transactions, there is currently inadequate visibility into the actual sales and rates being charged by transmission providers for ancillary services, especially where they have increased their reliance on markets to meet their ancillary services obligations. The Commission reasoned that this information would increase price transparency into the wholesale ancillary services markets and would better enable it to evaluate the competitiveness of these markets as well as strengthen its ability to monitor them.[15]

10. In the Proposed Rule, the Commission also proposed to delete from the definitions of certain ancillary services products, *i.e.,* Energy Imbalance, Generator Imbalance,

[6] June Order, 155 FERC ¶ 61,280 at P 5.

[7] Proposed Rule, 156 FERC ¶ 61,211.

[8] ECC states that it supports the comments filed by Duke and EEI in this proceeding. ECC Comments at 1.

[9] *Promoting Wholesale Competition Through Open Access Non-discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, 61 FR 21540 (May 10, 1996), FERC Stats. & Regs. ¶ 31,036 (1996) (cross-referenced at 77 FERC ¶ 61,080), *order on reh'g,* Order No. 888–A, 62 FR 12274 (Mar. 14, 1997), FERC Stats. & Regs. ¶ 31,048 (cross-referenced at 78 FERC ¶ 61,220), *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (DC Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002). The ancillary services available under the Order No. 888 OATT were Scheduling, System Control and Dispatch (Schedule 1); Reactive Supply and Voltage Control (Schedule 2); Regulation and Frequency Response (Schedule 3); Energy Imbalance (Schedule 4); Operating Reserve-Spinning Reserve (Schedule 5), and Operating Reserve-Supplemental Reserve (Schedule 6).

[10] *Preventing Undue Discrimination and Preference in Transmission Service,* Order No. 890, 72 FR 12266 (Mar. 15, 2007), 118 FERC ¶ 61,119, *order on reh'g,* Order No. 890–A, 73 FR 2984 (Jan. 16, 2008), 121 FERC ¶ 61,297 (2007), *order on reh'g,* Order No. 890–B, 73 FR 39092 (July 8, 2008), 123 FERC ¶ 61,299 (2008), *order on reh'g,* Order No. 890–C, 74 FR 12540 (Mar. 25, 2009), 126 FERC ¶ 61,228, *order on clarification,* Order No. 890–D, 74 FR 61511 (Nov. 25, 2009), 129 FERC ¶ 61,126 (2009).

[11] *Market-Based Rates for Wholesale Sales of Elec. Energy, Capacity & Ancillary Servs. by Pub. Utils.,* Order No. 697, 72 FR 39904 (Jul. 20, 2007), 119 FERC ¶ 61,295, *clarified,* 121 FERC ¶ 61,260 (2007), *order on reh'g,* Order No. 697–A, 73 FR 25832 (May 7, 2008), 123 FERC ¶ 61,055, *order on reh'g,* Order No. 697–B, 73 FR 79610 (Dec. 30, 2008), 125 FERC ¶ 61,326 (2008), *order on reh'g,* Order No. 697–C, 74 FR 30924 (June 29, 2009), 127 FERC ¶ 61,284 (2009), *order on reh'g,* Order No. 697–D, 75 FR 14342 (Mar. 25, 2010), 130 FERC ¶ 61,206 (2010), *aff'd sub nom. Mont. Consumer Counsel* v. *FERC,* 659 F.3d 910 (9th Cir. 2011), *cert. denied sub nom. Pub. Citizen, Inc.* v. *FERC,* 567 U.S. 934 (2012).

[12] Order No. 697, 119 FERC ¶ 61,295 at PP 1057–58.

[13] Order No. 2001–I, 125 FERC ¶ 61,103 at PP 29–30.

[14] *Id.* P 29.

[15] Proposed Rule, 156 FERC ¶ 61,211 at P 8.

Regulation & Frequency Response, Spinning Reserve and Supplemental Reserve, listed in Appendix A of the EQR Data Dictionary, the following language: ''For Transactions, sales by third-party providers (*i.e.,* non-transmission function) are reported.'' [16]

2. Comments

11. Several commenters do not oppose the Commission's proposed requirement, but nevertheless request that it should not apply to them. MISO states that it does not object to the proposed deletion from the definition of ancillary services-related product names in the EQR Data Dictionary.[17] However, MISO, CAISO, and PJM state that the Proposed Rule is unclear with respect to whether regional transmission organizations (RTOs) and independent system operators (ISOs) will be required to report ancillary services transaction data.[18] PJM explains that clarifying that the proposed requirement that transmission providers report ancillary services transaction data does not apply to RTOs is consistent with Commission precedent.[19] MISO, CAISO, and PJM argue that, if the Commission intended to include RTOs in the proposed requirement, the Commission should exempt RTOs from such an obligation.[20] In the alternative, CAISO requests that the Commission clarify that RTOs and ISOs could satisfy the proposed requirement by demonstrating that ancillary services transaction data is available through other means.[21]

12. MISO asserts that, because the Commission already receives ancillary services transaction data from each MISO participant in their EQR filings, an exemption for RTOs and ISOs is appropriate and that also requiring RTOs and ISOs to file this data would result in duplicate data and a significant administrative burden.[22] MISO asks that the Commission instead continue the current practice of accepting ancillary services transaction data submitted by each individual market participant.[23]

13. PJM likewise explains that it already reports the contract data associated with transmission contracts, including ancillary services transactions, in its EQRs.[24] PJM states that, for transaction data, the Commission has recognized that market participants within PJM already report this data in their EQRs from their sales within PJM.[25] PJM also states that PJM Settlement L.L.C. is simply a facilitating counterparty to the bids and offers of market participants with respect to pool transactions, and is not a market seller. PJM adds that, because sellers sell into the pool and buyers buy from the pool, there is no one-to-one relationship from seller to buyer and, therefore, PJM currently cannot match sellers to buyers for ancillary services transactions and cannot report ancillary services transaction data in the EQR.[26] CAISO and PJM also argue that the proposed requirement would duplicate information provided to the Commission pursuant to Order No. 760.[27]

14. In addition, CAISO notes that the Commission did not explain how there is inadequate visibility into the actual sales and rates being charged for ancillary services when those sales clear through a market operator.[28] PJM similarly argues that the proposed reporting requirement, if applied to PJM or other RTOs, would not help the Commission with its goal of increasing price transparency.[29] CAISO also explains that it is unclear how RTOs and ISOs can report ancillary services when they are subject to market clearing and cost allocation processes,[30] whereas PJM explains that the proposed requirement is not feasible given PJM's ancillary services transaction settlement process.[31] PJM also contends that this proposed requirement, if applied to PJM, risks disclosure of commercially sensitive information because it would require PJM to identify sellers of ancillary services, which in turn would require disclosure of cleared offers in the PJM market. PJM further states that the disclosure of cleared offers could be used for market manipulation purposes as competitors would be able to see each other's offers.[32] PJM also argues that disclosure of certain types of ancillary services transaction data (*e.g.,* regarding black start service) could implicate Critical Energy Infrastructure Information (CEII) and compromise the security of a public utility's physical and/or cyber assets.[33]

15. EEI, Bonneville, and Duke oppose the Commission's proposal, arguing that it duplicates ancillary services information reported in the EQR, FERC Form No. 1, eTariff, Open Access Same-Time Information System (OASIS) postings, or FPA section 205 proceedings. EEI believes that, because transmission providers provide ancillary services at cost-based rates specified in their OATTs or at RTO or ISO rates, which are reported in their FERC Form No. 1, requiring this information to be filed in EQRs would duplicate information the Commission already has.[34] EEI argues further that requiring transmission providers to report ancillary services provided by integrated utilities at rates other than OATT or RTO or ISO rates through marketing arms and already reported in third-party transactions in the EQR would be too burdensome.[35] EEI requests that, if the Commission does require general reporting of ancillary services transactions, it should ensure that only transactions not already reflected in the FERC Form No. 1 or at an RTO or ISO rate need to be reported.[36] EEI also requests that the Commission specify the actual EQR reporting fields and EQR Data Dictionary requirements being affected and where the new information is to be reported.[37]

16. Bonneville seeks clarification that the Proposed Rule's reference to transactions in ''wholesale ancillary services markets'' means markets where transmission customers can separately transact or negotiate charges for ancillary services.[38] Bonneville states that it does not operate a stand-alone wholesale ancillary services market and, while it does have separate posted rates for ancillary services, it does not sell or transact those services independently from its sale of transmission service. Bonneville states that its transmission function does not market or offer any ancillary services as a stand-alone service on its OASIS or otherwise; rather, ancillary services are included in the transmission service agreement with the customer and calculated as part of the customer's transmission service bill.[39] Bonneville seeks clarification from the Commission that a transmission provider does not have to

[16] *Id.*

[17] MISO Comments at 2.

[18] *Id.* at 2–3; CAISO Comments at 2; PJM Comments at 6–7.

[19] PJM Comments at 6–7.

[20] MISO Comments at 3–4; CAISO Comments at 3; PJM Comments at 8.

[21] CAISO Comments at 3.

[22] MISO Comments at 3–4.

[23] *Id.* at 4.

[24] PJM Comments at 7.

[25] *Id.* at 7–8.

[26] PJM Comments at 8–9.

[27] CAISO Comments at 2–3 (citing *Enhancement of Elec. Mkt. Surveillance and Analysis through Ongoing Electronic Delivery of Data from Regional Transmission Orgs. and Indep. Sys. Operators,* Order No. 760, 77 FR 26674 (May 7, 2012), 139 FERC ¶ 61,053 (2012)); PJM Comments at 9–10 (same).

[28] CAISO Comments at 2.

[29] PJM Comments at 8–9.

[30] CAISO Comments at 2.

[31] PJM Comments at 8–9.

[32] *Id.* at 10.

[33] *Id.*

[34] EEI Comments at 4.

[35] *Id.* at 4–5.

[36] *Id.* at 5.

[37] EEI Comments at 5. ECC also supports these comments. ECC Comments at 1.

[38] Bonneville Comments at 4.

[39] *Id.*

report ancillary services transactions that are provided pursuant to generally applicable rates for OATT service and not at negotiated or market-based rates.[40]

17. Bonneville argues that the proposed requirement would be a burden and would not further the Commission's goal of price transparency because the Commission reviews and approves the cost-based ancillary services rates of jurisdictional utilities and reviews and confirms Bonneville's ancillary services rates under section 7 of the Pacific Northwest Electric Power Planning and Conservation Act.[41] Bonneville requests, instead, that the Commission specify the precise transactions for which it does not have the information it seeks.[42] Bonneville requests that, because it is unclear how the proposed requirement would apply to Bonneville as it does not operate an ancillary services market, the Commission exempt transmission providers that make ancillary services transactions pursuant to their OATTs, and not at negotiated or market-based rates.[43] Bonneville also points out that the Commission substantially underestimates the cost to Bonneville to implement the proposed requirement, given the complexity of the ancillary services transactions it deals with during each quarter.[44] Bonneville states that its internal EQR reporting tool would need to interface with four other Bonneville systems, map information pulled from each system to create a composite transaction record after the fact, and convert that data into a format that meets the specifications in the EQR Data Dictionary.[45]

18. Duke disagrees with the Commission's basis for the proposed requirement, noting that the Contract Data section of the EQR is intended to include rates for sales of ancillary services by transmission providers and already provides adequate visibility.[46] For the ancillary services price data that is not visible, Duke suggests that the solution is to instead clarify the use of rate fields to ensure such visibility.[47] Duke further explains that it is unclear what type of monitoring the Commission intends with the proposed requirement and requests that the Commission provide examples of how it intends to use the new data to ensure the data collection meets the Commission's goals.[48]

19. In addition, Duke states that, for ancillary services at cost-based rates, transmission providers already provide this information through their EQRs, posted tariffs in eTariff, and OASIS postings.[49] Duke emphasizes that implementing the proposed requirement would require significant time and software changes and will likely require numerous further clarifications such that technical workshops should be held.[50]

20. On rehearing of the June Order, ECC requested clarification of whether certain cost-based rate ancillary services sales should be reported in the Transaction Data section of the EQR and how they should be reported, if required. ECC stated that some utilities provide black start service and reactive power sales to RTOs and ISOs, and the prices are included in the RTO or ISO OATT. ECC requested clarification that, because these cost-based rate services are being sold under the RTO or ISO OATT, they do not need to be reported by the utility. ECC, Wisconsin Electric Power Company and Wisconsin Public Service Corporation (jointly, WEC Companies) also requested clarification that, if a utility is selling cost-based rate ancillary services to an RTO or ISO under the utility's own OATT, these cost-based rate ancillary services do not need to be reported in the contract or transaction portion of the EQR because they are sales under a transmission tariff that are not part of a wholesale power sale. In the December Order, the Commission stated that it will address these requests to clarify the reporting of ancillary services transactions in this proceeding.[51]

3. Commission Determination

21. We will not adopt the proposed requirement for transmission providers to report information about their ancillary services transactions in the Transaction Data section of the EQR.[52] We find that the information currently provided by transmission providers in the Contract Data section of the EQR is sufficient to ensure just and reasonable rates and adequate transparency into ancillary services markets. Ancillary services provided by public utility transmission providers are at cost-based rates pursuant to OATTs and the Commission has determined these rates to be just and reasonable and not unduly discriminatory. Upon consideration of the comments received, we conclude that, on balance, the benefit that would be gained from requiring transmission providers to report ancillary services transaction data in the EQR would be outweighed by the burden of providing this information.

22. Our determination not to require transmission providers to report ancillary services transaction data is consistent with Order No. 2001, in which the Commission stated that ancillary services transaction data associated with transmission need not be reported in the EQR when the transmission services are provided on an unbundled basis.[53] In addition, this order leaves unchanged the requirement set forth in Order No. 2001 that ancillary services transaction data must be reported in the EQR when the ancillary services are bundled with power sales.[54] Although we will continue our current practice of requiring transmission providers to report only ancillary services contract information in the EQR, we emphasize that a transmission-owning public utility is responsible for filing its transmission-related information in the EQR, including ancillary services contract data, pursuant to FPA section 205.[55] As with other transmission-related data, an RTO or ISO may file the requisite ancillary services contract data on behalf of the transmission-owning public utility, if authorized by the transmission-owning utility to do so.[56]

23. We clarify that the intent of the Proposed Rule was not to change the current practice of requiring each individual RTO/ISO market participant to report its ancillary services data in the EQR or to require RTOs/ISOs to file ancillary services transaction data in addition to the transaction data currently filed by each RTO/ISO market participant. Pursuant to Order No. 697, a third-party provider (*i.e.,* non-transmission function) making sales of ancillary services at market-based rates, including individual RTO/ISO market participants, should continue to report both ancillary services contract and

[40] *Id.* at 4–5.

[41] *Id.* at 3.

[42] *Id.* at 3–4.

[43] *Id.* at 4–5.

[44] *Id.* at 5–6.

[45] *Id.* at 4–5.

[46] Duke explains that its comments are a supplement to EEI's comments. Duke Comments at 1.

[47] *Id.* at 2 n.3.

[48] *Id.* at 3.

[49] *Id.*

[50] *Id.* at 3–4. ECC also supports these comments. ECC Comments at 1.

[51] December Order, 157 FERC ¶ 61,180 at P 29.

[52] As a result, the Commission will not implement the changes proposed in the Proposed Rule to the definitions of certain ancillary services-related product names in Appendix A of the EQR Data Dictionary.

[53] *See* Order No. 2001, 99 FERC ¶ 61,107 at PP 271–272.

[54] *See id.* For example, if the ancillary services are sold together with energy, the ancillary services sales information must be reported in both the Contract and Transaction Data sections of the EQR.

[55] *See* December Order, 157 FERC ¶ 61,180 at PP 27–28.

[56] *See id.*

transaction data in the EQR.[57] However, in response to the requests for clarification from ECC and WEC Companies noted in the December Order, we clarify that third-party providers of ancillary services making sales under a Commission-accepted cost-based rate schedule or tariff, including an RTO/ISO OATT, need only report information about those ancillary services sales in the Contract Data section of the EQR.[58]

24. In reporting their ancillary services information in the EQR, transmission providers should mark the information as ''T—Transmission'' under Product Type Name (Field Number 30).[59] Third-party providers of ancillary services made at cost-based rates under a Commission-accepted rate schedule or tariff should report the information under the Product Type Name ''CB—Cost Based.'' [60] Third-party providers of ancillary services made at market-based rates under a market-based rate tariff should report the information under the Product Type Name ''MB—Market Based.'' [61] As a result, we are revising the definitions in the EQR Data Dictionary associated with the Product Type Names ''CB—Cost-Based'' and ''MB—Market Based'' to include the sale of ancillary services. In addition, transmission providers or third-party providers should report their ancillary services contracts and transactions (if applicable) in the EQR under their Company Identifier, or CID, which is obtained through the Commission's Company Registration System. Non-public utility transmission providers making ancillary services sales should report them under the Product Type Name ''NPU.'' [62]

25. In response to PJM's concern that reporting black start service information could implicate CEII and compromise the security of a public utility's assets, we clarify that filers should only report black start service information in the EQR at the seller level. That is, filers should not report unit-specific location information related to black start service in the EQR's unrestricted text fields.[63] The unrestricted (free-form) text fields include: FERC Tariff Reference (Field Numbers 19 and 48); Contract Service Agreement ID (Field Numbers 20 and 49); Rate Description (Field Number 37); Point of Receipt Specific Location (PORSL) (Field Number 40); and Point of Delivery Specific Location (PODSL) (Field Numbers 42 and 52). By submitting black start service information in the EQR only at the seller level and without unit-specific location information, filers will minimize the potential disclosure of sensitive information.

B. FERC Tariff Reference (Field Numbers 19 and 48)

1. Proposed Rule

26. In the Proposed Rule, the Commission proposed that sellers input in Field Numbers 19 and 48 a subset of the tariff information that sellers currently use to report their tariff-related data in the eTariff system. In particular, the Commission proposed to require sellers to submit, in Field Numbers 19 and 48, four of the Business Names associated with their tariff (*i.e.,* Tariff Identifier, Filing Identifier, Tariff Record Identifier, and Option Code) in the same format that they currently provide this data in the eTariff system. The Commission explained that this approach would allow greater consistency between the tariff designations used by sellers in the EQR and eTariff system. To effectuate this proposal, the Commission proposed to revise the definitions in Field Numbers 19 and 48 to add: ''The FERC tariff reference must include four of the Business Names currently submitted in the eTariff system: Tariff Identifier, Filing Identifier, Tariff Record Identifier, and Option Code.'' [64]

2. Comments

27. EEI and EPSA encourage the Commission to not require EQR filers to report the proposed eTariff fields for each contract and transaction because many contracts and transactions are not linked to tariffs or rate schedules in eTariff and, therefore, do not have the four Business Names.[65] EEI and EPSA argue that, because eTariff metadata is part of an XML filing protocol not currently meant for public consumption and some eTariff metadata may change with each eTariff submittal, eTariff metadata will be too confusing for EQR users as to these contracts and transactions.[66]

28. In addition, EEI and EPSA state that extracting the four Business Names from eTariff into the EQRs for each contract and transaction would be difficult, requiring new cross-functional software and business practices and involving a substantial number of records on an ongoing basis for larger companies, and would provide little use to EQR filers or EQR users.[67] Instead, EEI and EPSA encourage the Commission to continue allowing EQR filers to report the common names of their tariffs and rate schedules in EQR Field Numbers 19 and 48.[68] EEI states that this would continue the current industry practice.[69]

29. EEI and EPSA posit that, for tariffs and rate schedules filed in eTariff, the Commission could instruct EQR filers to use the same common names in the EQR Tariff Reference fields as they use in eTariff.[70] EEI asserts that, for most tariffs and rate schedules filed in eTariff, the eTariff Record Title and Record Content Description should suffice. EEI states that the eTariff Record Title may also be needed to avoid confusion where an entity has multiple databases so as to enable EQR users to cross reference the EQR referenced tariff documents when available in eTariff.[71]

30. Duke points out two flaws with the Commission's proposed use of the four Business Names: (1) The Commission's proposal to incorporate eTariff metadata will be imperfect as to sectionalized tariffs; and (2) the proposed metadata may be difficult even for sellers to obtain, especially those that contract out their eTariff filings to third parties, as it involves data inside eTariff software.[72]

31. Duke recommends that, for rate schedules not filed in eTariff, the Commission require the use of the common name of the agreement and/or

[57] If the Commission grants a seller market-based rate authority, the seller must comply with post-approval reporting requirements, including the filing of transaction-specific data in EQRs. *See* Order No. 697, 119 FERC ¶ 61,295 at P 962. Third-party providers of ancillary services at market-based rates are required to file EQRs to provide an adequate means for the Commission to monitor their ancillary services sales. *See id.* P 1058.

[58] These cost-based ancillary services sales can include sales of black start service and reactive power.

[59] Order No. 2001–I, 125 FERC ¶ 61,103 at P 35.

[60] Currently, the definition of the Product Type Name ''CB—Cost Based'' in the EQR Data Dictionary refers only to energy or capacity sold under a Commission-approved cost-based rate tariff. As specified in the redlined revisions to the EQR Data Dictionary in Attachment A, this definition will be revised to include ancillary services as well.

[61] Currently, the definition of the Product Type Name ''MB—Market Based'' in the EQR Data Dictionary refers only to energy or capacity sold under the seller's Commission-approved market-based rate tariff. As specified in the redlined revisions to the EQR Data Dictionary in Attachment A, this definition will be revised to include ancillary services as well.

[62] *See* Order No. 768, 140 FERC ¶ 61,232 at P 75.

[63] For example, a seller of black start service should not report black start service unit-related information in the EQR that identifies the location of a unit, such as ''CT Unit 1.'' Instead, the seller should report data, consistent with the EQR Data Dictionary requirements, only at the seller-level of granularity.

[64] Proposed Rule, 156 FERC ¶ 61,211 at P 10.

[65] EEI Comments at 6; EPSA Comments at 8.

[66] EEI Comments at 6; EPSA Comments at 8.

[67] EEI Comments at 6–7; EPSA Comments at 8.

[68] EEI Comments at 7; EPSA Comments at 3, 8.

[69] EEI Comments at 7.

[70] *Id.;* EPSA Comments at 8.

[71] EEI Comments at 7.

[72] Duke Comments at 5–6.

the rate schedule designation.[73] Duke suggests that, for unsectionalized tariffs and rate schedules, the Commission require the FERC Tariff Reference field to be completed with the Tariff Record Title and Record Content Description, which readily identify the relevant document.[74] Duke acknowledges that some companies may have more than one tariff and, as a result, more than one database, and in these cases, Duke recommends that the Tariff Title as well as the Tariff Record Title and Record Content Description must be included.[75] For a sectionalized tariff or rate schedule that exists in a tariff database by itself, Duke recommends that the Tariff Title would be logical to use in the FERC Tariff Reference field because it will lead users to the correct document in the database and its corresponding sections.[76] EPSA recommends the same approach.[77]

32. Duke suggests that, for sectionalized tariffs or rate schedules with a single parent or cover tariff record, the Tariff Record Title and Record Content Description of that Tariff Record should be included in the FERC Tariff Reference field because most eTariff users are likely to use such a naming convention.[78] Duke recommends that, for sectionalized tariff or rate schedules that have no parent or cover Tariff Record and are combined in the same tariff database with other tariff documents, it makes sense for the seller to include the Tariff Title, which identifies which database the tariff is located in, the common name of the document, and the Tariff Record Title and Record Content description of the first tariff record that comprises the tariff.[79]

33. EEI and Duke oppose including the eTariff Record Version Number. EEI argues that eTariff allows users to see which version was in effect at a given time, obviating the need to include the version in the EQR, and that reporting and updating the version numbers in the EQR would be burdensome and confusing.[80] Duke argues similarly.[81] In addition, EEI suggests that the Commission should develop guidance regarding the use of common names through a technical conference or equivalent dialogue with the regulated community.[82]

34. MISO and SPP state that they support the Commission's efforts to ensure that information reported in the EQR is consistent with eTariff information, and MISO states it does not take issue with the Commission's proposal to require sellers to input eTariff metadata into Field Numbers 19 and 48 in the same format that they currently provide this data in the eTariff system.[83] However, MISO, PJM, and SPP state that their current EQRs contain a number of conforming service agreements which are not currently filed through the eTariff system.[84] MISO, PJM, and SPP explain that, as a result, they would not be able to provide a Filing Identifier, Tariff Record Identifier, or Option Code in the FERC Tariff Reference fields for these agreements.[85] MISO and SPP request that the Commission revise its proposed changes to the EQR reporting requirements and the corresponding updates to the EQR Data Dictionary to not require the Filing Identifier, Tariff Record Identifier, and Option Code to be reported in the FERC Tariff Reference field for conforming service agreements not filed through the eTariff system.[86]

35. In addition, SPP seeks clarification that it can submit the Tariff Identifier assigned to SPP's Service Agreements Tariff for all service agreement contracts. SPP explains that that is all the information SPP can provide in the FERC Tariff Reference field for conforming service agreement contracts that are not submitted through the eTariff system.[87] Similarly, PJM states that it is unclear what data should be reported for conforming agreements in Field Numbers 19 and 48 or if the four Business Name reporting requirement applies only to agreements filed in the eTariff system.[88] PJM also seeks clarification on whether the requirement to report the four Business Names in Field Numbers 19 and 48 is prospective only, or whether sellers will be required to add the four Business Names previously reported in the EQR where such data is available.[89]

36. PJM also notes that, because sellers will have to manually enter each of the four Business Names into Field Numbers 19 and 48 for every agreement, which will not be the same for each agreement, requiring EQR filers to include the four Business Names in Field Numbers 19 and 48 will increase the number of hours necessary to prepare EQRs and, as a result, increase cost.[90]

37. Duke requests that the Commission provide at least a year for the adoption of any new EQR standard, in particular to adjust for the impact of the eTariff information.[91] Duke also asks that the Commission hold a technical conference on the proposal to require eTariff information if the Commission declines to adopt Duke's proposal because it believes further questions will arise.[92]

3. *Commission Determination*

38. We decline to adopt the proposal in the Proposed Rule to require filers to submit in the EQR certain tariff-related information that they currently submit in the eTariff system.[93] As noted in the EQR Data Dictionary, the purpose of these required FERC Tariff Reference fields (Field Numbers 19 and 48) is to ''cite the document that specifies the terms and conditions under which a Seller is authorized to make transmission sales, power sales or sales of related jurisdictional services at cost-based rates or market-based rates.'' The document can take the form of a Commission-accepted tariff, rate schedule, or service agreement. Based on the comments received in response to the proposal to require the reporting of four of the Business Names associated with a filer's tariff (*i.e.,* Tariff Identifier, Filing Identifier, Tariff Record Identifier, and Option Code), we conclude that this information would be difficult for filers to collect and report for each contract and transaction reported in the EQR. We find that, on balance, the costs of providing this information in Field Numbers 19 and 48 would outweigh the benefit of having such information in these fields. However, we emphasize that, although we will not require the specific eTariff information to be provided in Field Numbers 19 and 48, filers must nevertheless submit accurate and useful information in these fields,[94] consistent with prior Commission staff guidance.[95]

[73] *Id.* at 7.

[74] *Id.* at 7–8.

[75] *Id.* at 8.

[76] *Id.* at 11.

[77] EPSA Comments at 9.

[78] Duke Comments at 11–12.

[79] *Id.* at 12.

[80] EEI Comments at 7.

[81] Duke Comments at 8–9.

[82] EEI Comments at 7.

[83] *See* MISO Comments at 5; SPP Comments at 2.

[84] MISO Comments at 5; PJM Comments at 11–12; SPP Comments at 3.

[85] MISO Comments at 5; PJM Comments at 11–12; SPP Comments at 3.

[86] MISO Comments at 5; SPP Comments at 3.

[87] SPP Comments at 3.

[88] PJM Comments at 12.

[89] *Id.*

[90] *Id.*

[91] Duke Comments at 13.

[92] *Id.*

[93] As a result, we will not implement the changes proposed in the Proposed Rule to the FERC Tariff Reference fields (Field Numbers 19 and 48) in the EQR Data Dictionary.

[94] Examples of inaccurate and unacceptable entries previously made by filers with respect to the FERC Tariff Reference fields include entries such as ''Capacity Contract,'' ''1.Tariff,'' ''123,'' or ''ANOTHER TARIFF.''

[95] *See* Frequently Asked Questions on the EQR web page, *www.ferc.gov.*

39. We agree with EEI's and EPSA's suggestions to allow EQR filers to report the common names of their tariffs and rate schedules in the FERC Tariff Reference fields (Field Numbers 19 and 48). Therefore, in place of requiring the Business Names specified in the Proposed Rule, consistent with these suggestions and prior staff guidance, the FERC Tariff Reference fields should be populated using either the tariff designation or a truncated version of the section title of the seller's tariff document. For example, a section title using North American Energy Standards Board Business Names and adopted as the Commission's Business Names may include [Record Content Description]+[Tariff Record Title]+[Record Version Number]+[Option Code]. Each time a revision is made to the tariff being referenced, Field Numbers 19 and 48 must be updated to reflect the updated tariff. If the sales are at market-based rates, the tariff that is specified in the Commission order granting the seller market-based rate authority must be listed. Furthermore, filers should not submit a docket number for the FERC Tariff Reference field. Non-public utilities should specify ''NPU'' in Field Numbers 19 and 48.

C. Time Zone Field for Transmission Capacity Reassignments

1. Proposed Rule

40. The Commission sought comment in the Proposed Rule on requiring time zone information for transmission capacity reassignment transactions and adding options related to time zone information in Field Number 30. The Commission stated that, although Order No. 768 eliminated the Time Zone field from the Contract Data section of the EQR,[96] the Commission has determined that time zone information may be necessary for accurately reporting transmission capacity reassignment transactions, which are reported in the Contract Data section of the EQR. As a result, the Commission proposed to add options related to time zone information in Field Number 30 in the Contract Data section of the EQR.

2. Comments

41. Several commenters question the need for this requirement. EPSA and EEI point out that the Commission considered the input of industry stakeholders in Order No. 768 when it opted not to include the time zone data field in the Contract section of the EQR.[97] EPSA, ECC, and EEI question the need to specify time zones for transmission capacity reassignment transactions given that they are tracked on company OASIS sites, and ECC points out that the Balancing Authorities and Specific Locations are shown in the EQR.[98] EEI further states that the Commission has already provided guidance on tracking reassignments, specifying that the Time Zone field (Field Number 45) then in place should be completed as ''N/A.'' [99] EPSA also believes that requiring use of time zone information will confuse competitive suppliers because multiple time zones may apply to a transaction and the applicable time zones may change over time.[100]

42. EPSA and EEI request that, if the Commission does require a time zone for transmission capacity reassignment transactions, the Commission: (1) Explain the reversal from Order No. 768; (2) clarify which time zone should be used for a given transaction and what to do if the time zone changes or there are multiple time zones involved in the transaction; and (3) simplify reporting by requiring only ''prevailing'' time.[101] ECC similarly suggests that it would be easier to require filers to report in the prevailing time zone for the locations stated and to specify use of either Point of Receipt or Point of Delivery time zone for transmission service that spans multiple time zones.[102] ECC also questions whether the Atlantic Time Zone should be an option when there may not be Commission-jurisdictional service in that time zone.[103]

3. Commission Determination

43. We adopt the proposal to require time zone information with respect to transmission capacity reassignments and the addition of options related to time zones in the Product Type Name (Field Number 30) in the EQR for use in reporting transmission capacity reassignments.[104] In Order No. 890, the Commission determined that transmission capacity agreements and the transmission capacity reassignments under those agreements must be reported in the EQR.[105] The Commission determined that the Commission's access to this data is vital to ensure effective monitoring and oversight.[106] Following the issuances of Order Nos. 890, 890–A, and 890–B, the Commission issued a notice providing guidance on how to report transmission capacity reassignment agreements and the transactions made pursuant to those agreements within the existing EQR structure.[107] Both transmission capacity reassignment agreements and the individual transmission capacity reassignments pursuant to those agreements are required to be reported in the Contract Data section of the EQR. The Commission explained that transmission providers would use ''N/A'' for the Time Zone field when reporting their transmission capacity reassignment agreements in the Contract Section of the EQR.[108] However, transmission capacity reassignments under those agreements were required to be reported with the relevant Time Zone field information.[109]

44. In Order No. 768, the Commission eliminated the Time Zone field from the Contract Data section of the EQR, finding that it was unnecessary and that its elimination would reduce filers' burden, while continuing to require filers to report the time zone where the transaction took place in the Transaction Data section of the EQR.[110] As noted above, individual transmission capacity reassignments are reported in the Contract Data section of the EQR. By removing time zone information altogether from the Contract Data section of the EQR in Order No. 768, the Commission inadvertently eliminated the ability for filers to report time zone information related to individual transmission capacity reassignments. Reinstating the requirement to report time zone information for transmission capacity reassignments is necessary to accurately identify when a transmission capacity reassignment took place and ensure that complete information is captured for transmission capacity reassignments in the Contract Data section.

[96] *See* Order No. 768, 140 FERC ¶ 61,232 at P 121.

[97] *See* EPSA Comments at 13; EEI Comments at 8.

[98] *See* EPSA Comments at 13; ECC Comments at 3; EEI Comments at 8.

[99] EEI Comments at 8.

[100] EPSA Comments at 13.

[101] *Id.;* EEI Comments at 8.

[102] ECC Comments at 3.

[103] *Id.*

[104] As a result, we will implement the changes proposed in the Proposed Rule, along with some further revisions, to the Product Type Name (Field Number 30) in the EQR Data Dictionary, as discussed below.

[105] Order No. 890, 118 FERC ¶ 61,119, at P 817, *order on reh'g,* Order No. 890–A, 121 FERC ¶ 61,297 (2007), *order on reh'g,* Order No. 890–B, 123 FERC ¶ 61,299 (2008), *order on reh'g,* Order No. 890–C, 126 FERC ¶ 61,228, *order on clarification,* Order No. 890–D, 129 FERC ¶ 61,126 (2009).

[106] Order No. 890, 118 FERC ¶ 61,119 at P 821.

[107] *See Notice Providing Guidance on the Filing of Information on Transmission Capacity Reassignments in Elec. Quarterly Reports,* 124 FERC ¶ 61,244 (2008).

[108] *Id.* PP 7–8.

[109] *Id.* PP 9 & 11.

[110] Order No. 768, 140 FERC ¶ 61,232 at P 121.

45. To report the effective time zones for capacity reassignments, EQR filers can use the prevailing time zone options that will be added under Product Type Name (Field Number 30). ''Prevailing Time'' indicates that the time is adjusted according to the time of year for daylight savings. For example, Eastern Prevailing (EP) indicates the use of Eastern Standard (ES) between November and March and Eastern Daylight (ED) between March and November. We are not persuaded to adopt EPSA's suggestion to require only the use of ''Prevailing Time'' when reporting the Time Zone field. We note that filers have the option of reporting the prevailing time zone with respect to their transmission capacity reassignments, but prevailing time zone is not the only time zone option available to filers because other time zones may be applicable. In addition, we clarify that if multiple time zones apply or the applicable time zones change over time in terms of reporting transmission capacity reassignments, the filers should use the time zone that applies to the time zone at the Point of Delivery for transmission service. In response to ECC's question regarding whether the Atlantic Time Zone should be an option, we will keep ''Atlantic Time Zone'' as a time zone option given that this option is used by certain filers.

46. In addition, the ''CR—Capacity Reassignment'' option will remain in the list of options available under the Product Type Name field. This option was inadvertently omitted from the list of options available in Field Number 30 in the EQR Data Dictionary attached to the Proposed Rule. We remind transmission providers that they should continue to report their transmission capacity reassignment agreements in the EQR under the Product Type Name of ''CR—Capacity Reassignment.''

D. Booked Out Transactions

1. Proposed Rule

47. In the Proposed Rule, the Commission explained that, based on a review of EQR data, submissions related to ''Booked Out Power'' can frequently contain inconsistent or inaccurate information and that these inconsistencies or inaccuracies can distort the price and volume information related to power sales that is reported in the EQR. The Commission emphasized that, without accurate reporting of booked out transactions, it is difficult to determine how much power is traded compared to how much power is actually delivered.[111]

48. In this regard, the Commission stated that, based on the current EQR database configuration, it is not possible to differentiate book outs of energy from book outs of capacity because EQR filers do not have the option to distinguish between the two products. As a result, the Commission proposed in the Proposed Rule to replace the existing product name ''Booked Out Power'' in Appendix A of the EQR Data Dictionary with the product names ''Booked Out Energy'' and ''Booked Out Capacity.'' The Commission proposed that, accordingly, for book outs of energy, the EQR filer should report it under the product name ''Booked Out Energy,'' and for book outs of capacity, the EQR filer should report it under the product name ''Booked Out Capacity.'' Regarding the definitions in the EQR Data Dictionary, under the proposal, ''Booked Out Energy'' would be defined in Appendix A as: ''Energy contractually committed for delivery but not actually delivered due to some offsetting or countervailing trade (Transaction only).'' Similarly, ''Booked Out Capacity'' would be defined in Appendix A as: ''Capacity contractually committed for delivery but not actually delivered due to some offsetting or countervailing trade (Transaction only).'' [112]

49. In addition, the Commission proposed to clarify how booked out transactions should be reported, regardless of the number of parties involved in these transactions, using several examples. The first of these examples deals with a direct countervailing transaction, which occurs when two companies, both of whom are selling physical energy to each other for the same delivery period, mutually agree to exchange their physical delivery obligations to each other but maintain all other obligations, including payment. The second example the Commission provided relates to a curtailment, which can occur when one company is selling energy to another company and, in real time, the company buying the energy signals the seller to reduce the amount of energy it is providing to the buyer in exchange for a curtailment payment commensurate with the reduced production. The last example the Commission provided relates to a daisy chain, which occurs when there are at least three companies in a chain of energy sales and at least one company appears twice in that chain (*e.g.,* as a seller and as a buyer).

2. Comments

50. EEI expresses concern that the proposed clarification regarding booked out transactions might be misread to impose new reporting requirements on a large number of filers, who would have to construct the information manually, when the Commission may be trying to address confusion that has arisen in only a handful of cases, such as legacy capacity contracts allowing book-outs of capacity.[113] EEI and EPSA encourage the Commission to narrow the proposed clarification to avoid imposing what appears to be unintended new burdens on a large number of filers, including requiring filers to manually compile and report the information in the formats shown in the examples.

51. With respect to the Proposed Rule's second example clarifying how to report the curtailment or reduction of purchased megawatts EPSA comments that, while the Commission proposes for the seller to report as a sale the reduced megawatts sold, with the balance reported as a book out, sellers may currently report these transactions as the total megawatts originally contracted for sale, and then separately report the megawatts ultimately booked out.[114] EPSA states that, if the proposed reporting process is implemented, sellers may be required to revise the way they capture trade data in order to incorporate book outs on an individual hourly basis.[115] EPSA adds that this could result in costly and burdensome changes to sellers' trade capture systems to implement this change, which may not be necessary to track megawatts sold.[116]

52. Furthermore, EPSA asserts that how a seller reports the transaction would depend on whether the transaction is a firm or non-firm sale. EPSA proposes that, if the contract quantity for a non-firm sale is curtailed or reduced, the seller should report the sale at the reduced quantity without reporting a booked out quantity for the reduction in the non-firm sale.[117] EPSA does not set forth a specific proposal for dealing with firm sales, but notes that it has concerns with the Commission's approach. EPSA also explains that some sellers may not currently report the reduced megawatts as book outs because these transactions constitute a financial transaction for liquidated damages (which are not subject to EQR reporting), and that not all transactions

[111] Proposed Rule, 156 FERC ¶ 61,211 at P 13.

[112] *Id.* P 14.

[113] EEI Comments at 9.

[114] EPSA Comments at 9–10.

[115] *Id.* at 10–11.

[116] *Id.*

[117] *Id.* at 11.

will assess a penalty payment for a reduction in the megawatt quantity; for example, when the reduction is due to a transmission curtailment. EPSA states that characterizing these as book outs is a departure from current Commission guidance on EQR reporting and EPSA seeks clarification of whether the Commission intends to change its treatment of these types of transactions. EPSA urges the Commission to reconsider any such change.[118]

53. With respect to the example regarding daisy chain transactions, EPSA states that reporting book outs as described by the Commission may require sellers to revise the way they track trade data to incorporate book outs on an individual hourly basis, and that it could create additional administrative burden by requiring sellers to segregate trades into smaller pieces in order to report the transactions in the proposed manner. EPSA asks the Commission to reconsider its guidance.[119]

54. As to distinguishing the reporting of booked out capacity and energy transactions, EEI and EPSA request that the Commission provide examples.[120] ECC explains that capacity is not typically ''Booked Out'' in terms consistent with the Commission's definition. ECC explains its understanding that the Commission originally required ''Booked Out Power'' to be included in EQRs to ensure that markets were not being manipulated by traders and to ensure that sales affecting market prices were considered. ECC asserts that ''Booked Out Power'' sales are a significant determinant of energy market prices as energy marketers trade around their positions. ECC notes that this is not the case with the capacity market. ECC states that ''Booked Out Power'' does not need to be split into ''Booked Out Energy'' and ''Booked Out Capacity'' and that the examples of ''Booked Out Power'' shown by the Commission have always reflected energy sales. ECC adds that, in order to tell whether ''Booked Out Power'' is booked out energy or capacity, all that needs to be done is to look at the Rate Units associated with the sale.[121] EPSA seeks clarification on whether capacity transactions being considered in the Proposed Rule are only those which occur in the organized wholesale capacity markets.[122]

55. While ECC agrees with the first and third examples provided by the Commission in the Proposed Rule, it argues the Commission's suggested reporting of the second type of transaction (curtailment) is confusing and does not reflect the majority of actual curtailments. ECC explains that, in most cases, a curtailment occurs because there is a transmission constraint (or possibly the loss of generation) that precludes the energy sold and scheduled for delivery from being transmitted to the purchasing utility. ECC states that, if the Commission's example of curtailment were to occur, the purchasing utility would instead back off generation or sell energy, neither of which would normally be considered a curtailment.[123]

56. ECC argues that the definition of ''Booked Out Power'' in the EQR Data Dictionary, which specifies that the ''power is not actually delivered due to some offsetting or countervailing trade'' is not applicable to curtailments because the lack of delivery was not due to an offsetting trade. Instead, ECC argues the cause and effect are transposed because the ''offsetting trade'' was due to the lack of delivery.[124]

57. ECC also notes that, in its experience, when curtailments occur, the original transaction is not changed in the trade capture system, so reporting the way the Commission suggests would be a difficult and presumably manual process. ECC agrees with the Commission that, because the ''offsetting trade'' entered into the purchaser's trade capture system is not a sale with a delivery obligation, the purchaser in this case would not be obligated to report the ''sale'' in its EQR. ECC thus seeks clarification that because, for most utilities, those ''sales'' are indistinguishable from actual sales in their trade capture system, it is permissible, but not required, to include such ''sales'' in utilities' EQRs.[125] In addition, ECC suggests that reporting of ''Booked Out Power'' be discussed at a future EQR User's Group meeting.[126] According to EPSA, there is no explanation of how booked out reductions should be reported if the seller, rather than the buyer, initiates the resulting reduction.

3. Commission Determination

58. We do not adopt the proposal to require filers to report booked out energy separately from booked out capacity in the EQR instead of reporting both of these booked out transactions as ''Booked Out Power.'' [127] Upon consideration of the comments received, we believe that the burden of requiring filers to distinguish between these two types of transactions would outweigh the benefit of such a requirement. We acknowledge that booked out capacity transactions cannot be differentiated with certainty from booked out energy transactions without requiring these products to be reported separately.[128] However, the information reported as the Product Name (Field Number 31), Rate Units (Field Numbers 38 and 66), Standardized Quantity (Field Number 67), and Standardized Price (Field Number 68) with respect to these contracts and associated transactions can be used to distinguish between booked out energy and capacity transactions. For example, in Standardized Quantity (Field Number 67) booked out energy transactions should be reported as megawatt-hours, whereas booked out capacity transactions should be reported as megawatt-month in that same field.

59. Although we decline to adopt the proposal in the Proposed Rule, we will continue to consider this issue. In light of the comments received that reporting booked out transactions in a manner consistent with the examples in the Proposed Rule may differ from how sellers currently report their booked out transactions and may result in costly and burdensome changes,[129] we direct Commission staff to engage in further discussions regarding booked out transactions with industry at a future EQR Users Group meeting. These discussions will help inform any further guidance the Commission may provide on how to report these transactions in the EQR.

E. Other Issues

1. Comments

a. Timing & Implementation

60. EPSA requests that the Commission provide time to implement the proposed changes in the Proposed Rule as well as changes adopted in the June Order.[130] ECC encourages Commission staff to discuss implementation issues with utilities to develop a more appropriate estimate of the administrative burden involved in

[118] *Id.* at 11–12.

[119] *Id.* at 12.

[120] EEI Comments at 9; EPSA Comments at 10.

[121] ECC Comments at 4.

[122] EPSA Comments at 9.

[123] ECC Comments at 4–5.

[124] *Id.* at 5.

[125] *Id.* at 6.

[126] *Id.* at 5.

[127] As a result, we will not implement the changes proposed in the Proposed Rule related to the product name ''Booked Out Power'' in the EQR Data Dictionary.

[128] *See* Proposed Rule, 156 FERC ¶ 61,211 at P 14.

[129] *See* EPSA Comments at 11; EEI Comments at 9.

[130] EPSA Comments at 3.

the proposed EQR changes.[131] For example, ECC believes that the Commission understated the time required for transmission providers to implement the reporting of ancillary services transactions and for complying with the change in Product Name from ''Booked Out Power'' to ''Booked Out Energy'' and ''Booked Out Capacity.'' [132] As a result, ECC requests that the Commission add these burden estimates to the agenda of a future EQR Users Group meeting or technical conference.[133]

b. Future Changes

61. EPSA also asks that the Commission reconsider its plan to make future minor or non-material EQR changes directly via the Commission's website and, instead, consider adoption of any EQR changes through dialogue with industry stakeholders via an EQR/Data Collection Users Group, technical workshops, and/or notice-and-comment proceedings.[134]

c. Coordinating EQR and Data Collection Efforts

62. EPSA raises concerns about the potential for changes in this proceeding as well as the Data Collection proceeding in Docket No. RM16–17–000 [135] to impact the same or linked systems but on different implementation schedules.[136] EPSA believes a more coordinated approach is appropriate. As a result, EPSA requests that the Commission clarify the extent of ongoing data collection efforts and their interrelationships and provides the following options to do so: (1) The Commission could view the changes as a whole and propose them collectively; or (2) the Commission could move forward with a final rule in the Data Collection proceeding before issuing a Notice for Comments on EQR filing revisions.[137] EPSA also encourages the Commission to examine its data collection requirements and the data received from all entities. EPSA suggests that, in doing so, the Commission should assess the effectiveness of the EQR Data Dictionary and whether a lack of clarity is the reason why companies are reporting data differently.[138]

[131] ECC Comments at 6–7.

[132] *Id.* at 7.

[133] *Id.* at 7–8.

[134] EPSA Comments at 3.

[135] *Data Collection for Analytics & Surveillance and Market-Based Rate Purposes,* Order No. 860, 84 FR 36390 (July 26, 2019), 168 FERC ¶ 61,039, at P 88 (2019), *order on reh'g and clarification,* Order No. 860–A, 85 FR 13012 (Mar. 6, 2020), 170 FERC ¶ 61,129 (2020).

[136] EPSA Comments at 4.

[137] *Id.* at 5–6.

[138] *Id.* at 6.

2. Commission Determination

63. We will implement the revisions and clarifications specified in this order regarding reporting time zone information for transmission capacity reassignments by April 30, 2021, when the Q1 2021 EQR filings are due. Accordingly, the revisions and clarifications must be applied to EQR filings beginning with the first quarter of 2021. In light of the adjustments to the EQR filing requirements made in this order as compared to the Proposed Rule, we adjust the burden calculations from those included in the Proposed Rule, as noted below. In addition, because we are not adopting the proposals to require transmission providers to report ancillary services transactions data or for filers to distinguish between ''Booked Out Energy'' and ''Booked Out Capacity,'' we do not need to discuss the burden estimates included in the Proposed Rule with regard to these proposals at a future meeting or conference, as suggested by ECC.

64. In response to EPSA's request that the Commission reconsider its plan to make future minor or non-material changes to the EQR by posting them directly to the Commission's website [139] and, instead, to consider adoption of any changes to the EQR through dialogue with industry stakeholders in the form of EQR/data collection users groups, technical workshops, and/or notice-and-comment proceedings, we note that Commission staff and industry stakeholders can discuss possible future changes to the EQR, including minor or non-material changes, during EQR Users Group meetings. As stated in the December Order: ''Commission staff has reinstated the EQR Users Group meetings, which will enable Commission staff and EQR users to engage in an ongoing dialogue about EQR-related issues, including possible future changes to the EQR filings requirements and the EQR Data Dictionary before those changes are implemented.'' [140]

65. In response to EPSA, we note that the revisions and clarifications to the EQR reporting requirements addressed in this proceeding do not implicate the data collection processes established by Order No. 860 and, therefore, these two proceedings do not need to be considered collectively. As stated in Order No. 860, while market-based rate sellers may report to the relational database some of the same contracts they report in their EQRs, the information collected in these two different systems is not unnecessarily duplicative based on the differences between the two data collections.[141]

[139] *See* June Order, 155 FERC ¶ 61,280 at P 5; December Order, 157 FERC ¶ 61,180 at PP 40–43.

[140] December Order, 157 FERC ¶ 61,180 at P 2.

[141] Order No. 860, 168 FERC ¶ 61,039 at PP 88–92 (explaining that the EQR only captures sales information whereas the relational database captures information about long-term firm purchases and sales, and why the information being collected in the relational database is necessary where there is overlap with information collected in the EQR).

III. Information Collection Statement

66. The Paperwork Reduction Act (PRA) [142] requires each federal agency to seek and obtain Office of Management and Budget (OMB) approval before undertaking a collection of information directed to ten or more persons or contained in a rule of general applicability. OMB regulations [143] require approval of certain information collection requirements imposed by agency rules. Upon approval of a collection of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of these proposals will not be penalized for failing to respond to this collection of information unless the collection of information displays a valid OMB control number.

67. This order will affect public utilities and certain non-public utilities. The order requires filers to submit time zone information in connection with transmission capacity reassignment transactions.

68. There are approximately 2,196 public utilities and about 40 non-public utilities that currently file EQRs. About 405 of the 2,196 public utilities only submit data in the ID section of the EQR because they have no data to report in the Contract or Transaction Data sections of the EQR. We estimate that approximately 31 public utilities and three non-public utilities are currently reporting transmission capacity reassignment transactions and would be affected by the requirement to include the time zone information in connection with these transactions.

69. *Burden Estimate:* In general, the burden of preparing an EQR filing varies, depending on the complexity of a company's transactions. For example, if a company has a few long-term, cost-based rate contracts with a limited number of counterparties and few adjustments to price, counterparties, and sales locations, it will expend relatively little effort in complying with EQR filing requirements. If a company's sales activities become more complex, with more frequent adjustments to price

[142] 44 U.S.C. 3501–3520.

[143] 5 CFR 1320.

and a greater variety of counterparties and sales locations, its technological capabilities for tracking its transactions tend to become more sophisticated.

70. The estimated burden [144] and cost [145] for the reporting requirements adopted in this order, follow.[146]

Burden Changes Due to Commission Order on Electric Quarterly Report (FERC-920) Reporting Requirements							
	Annual No. of Respondents	Annual No. of Responses Per Respondent	Annual Total No. of Responses	Average Hours per Response	Weighted Hourly Cost ($) for Wages & Benefits	Total Annual Burden Hours	Total Annual Cost ($) for Wages & Benefits
	(1)	(2)	(1) * (2) = (3)	(4)	(5)	(3) * (4) = (6)	(3) * (4) * (5) = (7)
Initial One Time Costs							
Public Utilities							
"Time Zone" Field in Contracts	31	1	31	13.0	$78.48	403	$31,625.67
Non-Public Utilities							
"Time Zone" Field in Contracts	3	1	3	13.0	$78.48	39	$3,060.55
Ongoing Annual Costs							
Public Utilities							
"Time Zone" Field in Contracts	31	4	124	0.5	$78.48	62	$4,865.49
Non-Public Utilities							
"Time Zone" Field in Contracts	3	4	12	0.5	$78.48	6	$470.85
					Initial Hours/Costs Public Utilities	403	$31,625.67
					Initial Hours/Costs Non-Public Utilities	39	$3,060.55
					Total Initial Hours/Costs	**442**	**$34,686.22**
					Ongoing Hours/Costs Public Utilities	62	$4,865.49
					Ongoing Hours/Costs Non-Public Utilities	6	$470.85
					Total Ongoing Hours/Costs	**68**	**$5,336.34**

For public and non-public utilities, the weighted hourly cost (rounded, for salary plus benefits) is $78.48.

Title: FERC–920, Electric Quarterly Report (EQR).

Action: Revision of currently approved collection of information.

OMB Control No.: 1902–0255.

Respondents: Public utilities and certain non-public utilities.

Frequency of Information: Initial implementation and quarterly updates.

Necessity of Information: The Commission's EQR reporting requirements must keep pace with market developments and technological advancements. Collecting and formatting the data as discussed in this order will provide the Commission with the necessary information to identify and address potential exercises of market power and better inform Commission policies and regulations.

Internal Review: The Commission has determined that the revisions and clarifications are necessary in light of technological advances in data collection processes. The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimate associated with the information requirements.

71. Interested persons may obtain information on the reporting requirements by contacting the Federal Energy Regulatory Commission, Office of the Executive Director, 888 First Street NE, Washington, DC 20426 [Attention: Ellen Brown, email: *DataClearance@ferc.gov,* or phone: (202) 502–8663].

72. Comments concerning the information collection adopted in the order, and the burden estimates, should be sent to the Commission in this docket. Comments may also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503 [Attention: Desk Office for the Federal Energy Regulatory Commission]. Please identify OMB Control Number 1902–0255 in the subject line of your comments, and send them to *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review field,'' select Federal Energy Regulatory Commission, click ''submit,'' and select ''comment'' to the right of the subject collection.

IV. Environmental Analysis

73. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[147] The Commission has categorically excluded certain actions from these requirements as not having a

[144] ''Burden'' is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[145] The estimated hourly costs (salary plus benefits) are based on the figures for May 2019 posted by the Bureau of Labor Statistics for the Utilities sector (*http://www.bls.gov/oes/current/naics2_22.htm*) and updated (for Dec 2019, issued March 19, 2020) for benefits information (*http://www.bls.gov/news.release/ecec/nr0.htm*). The hourly estimates for salary plus benefits are: (a) Legal (code 23–0000), $142.65; (b) Computer and mathematical (code 15–0000), $64.69; (c) Computer and information systems manager (code 11–3021), $101.58; (d) Information security analyst (code 15–1122), $71.47; (e) Auditing and accounting (code 13–2011), $56.66; and (f) Information and record clerk (43–4199), $41.03. The percentage of time each skill set contributes is: Legal, 12.5%; computer and mathematical, 37.5%; computer and information system managers, 16.7%; information security analysts, 12.5%; accountants and auditors, 12.5%; and information and record clerks, 8.3%. The corresponding estimated weighted hourly cost for wages and benefits is $78.48.

[146] The burden and cost estimates below do not include burden and cost associated with transmission providers reporting ancillary services transaction data, reporting eTariff data in the EQR, and distinguishing between booked out transactions because the Commission is not adopting those proposed requirements in this order.

[147] *Regulations Implementing the Nat'l Envtl. Policy Act of 1969,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

significant effect on the human environment.[148] The actions proposed here fall within a categorical exclusion in the Commission's regulations, *i.e.,* they involve information gathering, analysis, and dissemination.[149] Therefore, environmental analysis is unnecessary and has not been performed.

V. Regulatory Flexibility Act

74. The Regulatory Flexibility Act of 1980 (RFA) [150] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The Commission is not required to perform this sort of analysis if the proposed activities within the final rule would not have such an effect.

The estimated total number of entities that would need to modify how they report transmission capacity reassignment information in the EQR is 34.[151] We estimate that 24% of these entities fall within the RFA's definition of small.[152]

75. The estimated average costs for each entity reporting transmission capacity reassignments would be minimal, requiring 13 hours or $1,020 in initial one-time costs, and 2 hours or $157 in ongoing annual costs. Accordingly, we find that the revised requirements set forth in this rule will not have a significant economic impact on a substantial number of small entities, and no regulatory flexibility analysis is required.

VI. Document Availability

76. 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 FERC's Home Page (*http://www.ferc.gov*). 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.

77. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

78. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VII. Effective Date and Congressional Notification

79. These regulations are effective September 14, 2020. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996. The rule will be provided to the Senate, House, the Government Accountability Office, and the Small Business Administration.

By the Commission.

Issued: June 18, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

BILLING CODE 6717–01–P

Attachment A

Revisions to

Electric Quarterly Report Data Dictionary

[148] *Id.*

[149] 18 CFR 380.4.

[150] 5 U.S.C. 601–612.

[151] These entities fall under the current definition of ''Electric Bulk Power Transmission and Control'' (NAICS code 2211221).

[152] 5 U.S.C. 601(3) (citing to section 3 of the Small Business Act, 15 U.S.C. 632). Section 3 of the Small Business Act defines a ''small business concern'' as a business that is independently owned and operated and that is not dominant in its field of operation. 15 U.S.C. 632. The Small Business Administration's Size Standards at 13 CFR 121.201 define the maximum number of employees an entity and its affiliates may have to be considered small. The threshold for a small entity for Electric Bulk Power Transmission and Control (NAICS code 221121) is 500 employees.

EQR Data Dictionary
Contract Data

Field #	Field	Required	Value	Definition
30	**Product Type Name**	✓	**CR - Capacity Reassignment**	**An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer.**
30	Product Type Name	✓	CR-AD - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer.~~ **Transmission capacity reassignments** reported in Atlantic Daylight time.
30	Product Type Name	✓	CR-AP - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer.~~ **Transmission capacity reassignments** reported in Atlantic Prevailing time.
30	Product Type Name	✓	CR-AS - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer.~~ **Transmission capacity reassignments** reported in Atlantic Standard time.
30	Product Type Name	✓	CR-CD - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer.~~ **Transmission capacity reassignments** reported in Central Daylight time.
30	Product Type Name	✓	CR-CP - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer.~~ **Transmission capacity reassignments** reported in Central Prevailing time.
30	Product Type Name	✓	CR-CS - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer.~~ **Transmission capacity reassignments** reported in Central Standard time.
30	Product Type Name	✓	CR-ED - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer.~~**Transmission capacity reassignments** reported in Eastern Daylight time.
30	Product Type Name	✓	CR-EP - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer~~**Transmission capacity reassignments** reported in Eastern Prevailing time.
30	Product Type Name	✓	CR-ES - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer~~ **Transmission capacity reassignments** reported in Eastern Standard time.
30	Product Type Name	✓	CR-MD - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer~~**Transmission capacity reassignments** reported in Mountain Daylight time.

30	Product Type Name	✓	CR - MP - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer~~**Transmission capacity reassignments** reported in Mountain Prevailing time.
30	Product Type Name	✓	CR - MS - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer,~~**Transmission capacity reassignments** reported in Mountain Standard time.
30	Product Type Name	✓	CR-PD - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer,~~**Transmission capacity reassignments** reported in Pacific Daylight time.
30	Product Type Name	✓	CR-PP - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer,~~**Transmission capacity reassignments** reported in Pacific Prevailing time.
30	Product Type Name	✓	CR-PS - Capacity Reassignment	~~An agreement under which a transmission provider sells, assigns or transfers all or portion of its rights to an eligible customer,~~**Transmission capacity reassignments** reported in Pacific Standard time.

30	Product Type Name	✓	CB – Cost Based	Energy**,** ~~or~~ capacity **or ancillary services** sold under a FERC-approved cost-based rate tariff.
30	Product Type Name	✓	MB – Market Based	Energy**,** ~~or~~ capacity **or ancillary services** sold under the seller's FERC-approved market-based rate tariff.

[FR Doc. 2020–13675 Filed 7–14–20; 8:45 am]

BILLING CODE 6717–01–C

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation (PBGC).

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe certain interest assumptions under the regulation for plans with valuation dates in August 2020. These interest assumptions are used for paying certain benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective August 1, 2020.

FOR FURTHER INFORMATION CONTACT: Gregory Katz (*katz.gregory@pbgc.gov*), Attorney, Regulatory Affairs Division, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, (202) 229–3829. (TTY users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to (202) 229–3829.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminated single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974 (ERISA). The interest assumptions in the regulation are also published on PBGC's website (*https://www.pbgc.gov*).

PBGC uses the interest assumptions in appendix B to part 4022 (''Lump Sum Interest Rates for PBGC Payments'') to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Because some private-sector pension plans use these interest rates to determine lump sum amounts payable to plan participants (if the resulting lump sum is larger than the amount required under section 417(e)(3) of the Internal Revenue Code and section 205(g)(3) of ERISA), these rates are also provided in appendix C to part 4022 (''Lump Sum Interest Rates for Private-Sector Payments'').

This final rule updates appendices B and C of the benefit payments regulation to provide the rates for August 2020 measurement dates.

The August 2020 lump sum interest assumptions will be 0.00 percent for the period during which a benefit is (or is assumed to be) in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for July 2020, these assumptions represent no change in the immediate rate and are otherwise unchanged.

PBGC updates appendices B and C each month. PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to issue new interest assumptions promptly so that they are available for plans that rely on our publication of them each month to calculate lump sum benefit amounts.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during August 2020, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, rate set 322 is added at the end of the table to read as follows:

Appendix B to Part 4022 — Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*		*
322	8–1–20	9–1–20	0.00	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, rate set 322 is added at the end of the table to read as follows:

Appendix C to Part 4022 — Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*		*
322	8–1–20	9–1–20	0.00	4.00	4.00	4.00	7	8

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2020–15123 Filed 7–14–20; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 103

[DOD–2008–OS–0124]

RIN 0790–AJ40

Sexual Assault Prevention and Response (SAPR) Program

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: The Department of Defense (DoD) is finalizing two interim final rules in a single final rule which deletes all guidance internal to DoD, and incorporate only those policy provisions directly affecting DoD's obligations to provide sexual assault prevention and response (SAPR) services to certain members of the public who are adult victims of sexual assault. This revision also makes SAPR policy updates as required by legal mandates.

DATES: This rule is effective August 14, 2020.

FOR FURTHER INFORMATION CONTACT: Diana Rangoussis, Senior Policy Advisor, Sexual Assault Prevention and Response Office (SAPRO), (703) 696–9422.

SUPPLEMENTARY INFORMATION: The Department of Defense is revising 32 CFR part 103 by finalizing the interim final rule published on September 27, 2016 (81 FR 66185–66189), deleting all guidance internal to DoD, and incorporating those policy provisions from 32 CFR part 105 that directly affect DoD's obligations to provide sexual assault prevention and response (SAPR) services to certain members of the public, who are adult victims of sexual assault. With the publication of this rule, 32 CFR part 103 will be the only part that outlines the Department's obligations to provide SAPR services to certain members of the public. The Department is also making a conforming change to comply with law. The rule implements NDAA FY 2020 section 536 which sets forth a procedure for persons making a Restricted Report to retrieve any personal property that was obtained when the individual makes a Restricted Report. The rule sets forth an internal agency procedure mandated by Congress in Section 536 and although internal agency procedures are exempt from rule making and public comment, it is included in this Final Rule for completeness.

This rule is being published as part of DoD's regulatory reform work as part of Executive Order (E.O.) 13777, ''Enforcing the Regulatory Reform Agenda'' (February 24, 2017), which requires Executive departments and agencies to appoint a Regulatory Reform Officer to oversee the implementation of regulatory reform initiatives and policies and establish a Regulatory Reform Task Force (Task Force) to review and evaluate existing regulations and make recommendations to the agency head regarding their repeal, replacement, or modification, consistent with applicable law. Those reform initiatives and policies include E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs'' (January 30, 2017), Section 6 of E.O. 13563, ''Improving Regulation and Regulatory Review'' (January 18, 2011), and E.O. 12866, ''Regulatory Planning and Review'' (September 30, 1993). More information on DoD's work can be found at *https://open.defense.gov/Regulatory-Program/RRTF2.aspx.* The Department's internal policies and procedures are published in DoD Directive 6495.01, ''Sexual Assault Prevention and Response (SAPR) Program'' (last updated April 11, 2017, and available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/649501p.pdf*), and DoD Instruction 6495.02, ''Sexual Assault Prevention and Response (SAPR) Program

Procedures,'' (last updated May 24, 2017, and available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649502p.pdf*).

Authority for This Rulemaking

This final rule incorporates applicable Congressional mandates from Section 113 of Title 10, United States Code (U.S.C.), and multiple Public Laws including the following.

10 U.S.C. 136 and DoD Directive 5124.02, the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) may:

—Establish and allocate civilian personnel authorizations of the DoD Components and review and approve military and civilian personnel authorization changes during program execution.

—Exercise the authorities of the Secretary of Defense, whenever vested, relating to civilian personnel, whether established by law, regulation, or other actions.

- Public Law 106–65, National Defense Authorization Act for Fiscal Year 2000:

—Report and regulations on Department of Defense policies on protecting the confidentiality of communications with certain individuals regarding sexual or domestic abuse.

- Public Law 108–375, Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005:

—Review on how sexual offenses are covered by the Uniform Code of Military Justice; processing of forensic evidence collection kits, examination of sexual assault in the Armed Forces by the Defense Task Force to examine violence at the military service academies.

- Public Law 109–163, National Defense Authorization Act for Fiscal Year 2006:

—Extension of Article 120 (Rape) and the statute of limitations for rape under the Uniform Code of Military Justice.

- Public Law 109–364, John Warner National Defense Authorization Act for Fiscal Year 2007:

—Revision and clarification of requirements with respect to surveys and reports concerning sexual harassment and sexual violence at the service academies.

—Direct the Military Service Academy Superintendents to conduct an annual assessment to determine the effectiveness of the policies, training, and procedures of the Academies with respect to sexual harassment and sexual violence involving Academy personnel.

- Public Law 110–417, Duncan Hunter National Defense Authorization Act for Fiscal Year 2009:

—Extension of Military Protective Orders' duration shall remain in effect until termination by issuing commander or replacement order.

—Mandatory notification of issuance of military protective order to civilian law enforcement.

- Public Law 111–84, National Defense Authorization Act for Fiscal Year 2010:

—Improved prevention and response to allegations of sexual assault involving members of the armed forces.

—Requirement to collect and submit data on whether a military protective order was issued involving either the victim or alleged perpetrator of a sexual assault, and whether the military protective order was violated in the course of a substantiated incident of sexual assault.

- Public Law 111–383, Ike Skelton National Defense Authorization Act for Fiscal Year 2011:

—Improved protocols for providing medical care for victims of sexual assault.

—Entitlement to victim advocacy services for military or dependent sexual assault victims.

—Annual report regarding sexual assaults involving members of the Armed Forces and improvement to sexual assault prevention and response program.

—Extension of sexual assault prevention and response program to Reserve components.

- Public Law 112–81, National Defense Authorization Act for Fiscal Year 2012:

—Reform of offenses relating to rape, sexual assault, and other sexual misconduct under the Uniform Code of Military Justice.

—Authority to compel production of documentary evidence.

- Public Law 113–66, National Defense Authorization Act for Fiscal Year 2014:

—Temporary administrative reassignment or removal of alleged offender.

—Retention of certain forms in connection with Restricted Reports for 50 years.

—Require an eight-day incident report in response to an Unrestricted Report in which the victim is a member of the Armed Forces.

—Discharge or dismissal for certain sex-related offenses and trial of such offenses by general courts-martial.

- Public Law 112–239, National Defense Authorization Act for Fiscal Year 2013 which:

—Establishes special victim capabilities within DoD to respond to allegations of certain special victim offenses.

—Enhances training and education for sexual assault prevention and response commander training and 14-day notice of SAPR program to new Service members.

—Add requirements to Workplace and Gender Relations Surveys.

—Requires General or Flag officer review of and concurrence involving separation of a Service member within one year after making an unrestricted report of sexual assault.

- Public Law 113–291, Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015 which provides:

—Access of Special Victims' Counsel to a member of Reserve and National Guard.

—Modification of DoD policy on retention of evidence in a sexual assault case whereby victim's property returned upon completion of related proceedings.

—Modification of Military Rules of Evidence 513 whereby victim-psychotherapist privilege extended to other mental health professionals.

—Analysis and assessment of disposition of most serious offenses identified in Unrestricted Reports on the Annual Report on Sexual Assaults in the Armed Forces.

—Plan for limited use of certain information on sexual assaults in Restricted Reports by military criminal investigative organizations.

- Public Law 114–92, National Defense Authorization Act for Fiscal Year 2016, which requires:

—Preemption of State law to ensure confidentiality of reporting.

—That any State law or regulation requiring disclosure of personal identifiable information of an adult military victim (or adult military dependent victim) or alleged perpetrator of a sexual assault to a state or local law enforcement agency, shall not apply except when disclosure of personally identifiable information is necessary to prevent or mitigate a serious and imminent threat to the health or safety of the victim or individual.

- Public Law 116–92, National Defense Authorization Act for Fiscal Year 2020, which requires:

—The return of personal property collected during a forensic examination in a Restricted Report upon the request of the victim.

Expected Impact of This Final Rule

For Fiscal Year 2018, the SAPR office is funded at $24 million. There is an additional allocation of $35 million designated for the Special Victims' Counsel Program and the Special Victims' Investigation and Prosecution capability. Each of the Military Services establishes its own SAPR budget for the programmatic costs arising from the implementation of the training, prevention, reporting, response, and oversight requirements. This final rule does not change costs or benefits already in effect from either the interim final rules.

Response to Public Comments

Sexual Assault Prevention and Response (SAPR) Program (32 CFR part 103, RIN 0790–AJ40) and Sexual Assault Prevention and Response (SAPR) Program Procedures (32 CFR part 105, RIN 0790–AI36) were published in the **Federal Register** on September 27, 2016, at 81 FR 66185–66189 and 81 FR 66424–66460, respectively. DoD received comments from a total of thirty individuals and organizations for both of the previously published interim-final rules combined. While no changes were made to the final rule based on public comments, the Department is appreciative to the public for expressing their favor, as well as concerns related to sexual assault within our ranks.

In general, the majority of the commenters expressed support for the Department's work to address sexual assault.

The Department did receive several comments where the public expressed concerns with: (1) Military culture; (2) the review process for sexual assault victims administratively separated after a report of sexual assault; (3) retaliation towards a sexual assault victim; and (4) amnesty for a sexual assault victim's collateral misconduct.

In response to comments, the Department should do more to change the culture within its ranks, DoD notes work in these areas is a fundamental goal of the Department's SAPR Program. Over the past several years, the Department has directed a total of 54 initiatives that have fundamentally changed the way DoD confronts sexual assault by enhancing commander accountability, creating strategies to prevent the crime, ensuring proper command climate, and improving Service member support.

Several commenters also expressed concern commanders should not expeditiously discharge sexual assault victims. The Department stresses there is no policy authorizing an expedient, involuntary discharge of sexual assault victims without due process. Beginning with FY 2013, section 578 of the National Defense Authorization Act (NDAA) elevated this process to a General Officer/Flag Officer review requirement. An enlisted Service member or a commissioned officer who made an Unrestricted Report of sexual assault and is recommended for involuntary separation from the Military Services within 1 year of final disposition of his or her sexual assault case can request a general or flag officer review of the circumstances of and grounds for the involuntary separation.

Several commenters noted fear of retaliation is one of the biggest barriers to reporting and expressed concern it is unclear how Service members who engage in retaliation will be held accountable for their actions. In 2017 the DoD Retaliation Prevention and Response Strategy (RPRS), *https://www.sapr.mil/sites/default/files/Retailation_Info_Paper_071117_1_0.pdf,* was implemented to improve the way DoD supports Service members who experience retaliation. The RPRS aligns Department efforts in combatting retaliation and targets five issues:

- Standardizing Definitions of Retaliatory Behavior
- Closing the Gap in Knowledge: Data Collection and Analysis
- Building Strong and Supportive Systems of Investigation and Accountability
- Providing Comprehensive Support to Reporters
- Creating a Culture Intolerant of Retaliation

In response to comments requesting clarification if and when collateral misconduct occurs when would this misconduct merit punishment, DoD notes Commanders have discretion to defer action on alleged collateral misconduct by sexual assault victims until final disposition of the sexual assault case. In doing so, commanders may consider the trauma to the victim. However, victims who are concerned about being punished for collateral misconduct may consult confidentially with a Special Victims' Counsel (SVC) or Victims' Legal Counsel (VLC). The SARC and SAPR VA are required to advise a victim of his/her ability to consult with an SVC/VLC during their initial contact, and the advisement is documented on DD Form 2910 ''Victim Reporting Preference Statement.''

Regulatory Procedures

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This final rule has been designated as a ''not significant'' regulatory action, and not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs''

This final rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

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).

Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

It has been determined that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. Section 601)

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule provides SAPR Program guidance only.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

It has been determined that this rule does impose reporting or recordkeeping requirements under the Paperwork

Reduction Act of 1995. OMB has approved these requirements under OMB Control Number 0704–0482, ''Defense Sexual Assault Incident Database.'' There are no changes in burden or content to this information collection with this final rule.

The System of Records Notice for DHRA 06, Defense Sexual Assault Incident Database is available at *https://www.gpo.gov/fdsys/pkg/FR-2015-11-04/pdf/2015-28081.pdf.* The Privacy Impact Assessment (PIA) is available at *https://www.dhra.mil/webfiles/docs/Privacy/PIA/DHRA.06.SAPRO.DSAID.7.15.2015.pdf;* or *https://www.dhra.mil/Headquarters/Privacy/PIA/.*

Executive Order 13132, ''*Federalism*''

It has been determined that this rule does have federalism implications, as set forth in Executive Order 13132, because it incorporates the preemption language in section 536 of Public Law 114–92, which preempts state and local laws requiring disclosure of personally identifiable information of the Service member (or adult military dependent) victim or alleged perpetrator to state or local law enforcement agencies, unless such reporting is necessary to prevent or mitigate a serious and imminent threat to the health and safety of an individual, as determined by an authorized DoD official. This rule does have substantial direct effects on: (a) The States; (b) the relationship between the National Government and the States; or (c) the distribution of power and responsibilities among the various levels of Government. DoD determined that it was impracticable and unnecessary to consult with state and local governments on the development of this regulation because any preemption was expressly mandated by statute, the restrictions on reporting personal identifying information was limited to military bases, and those restrictions have been in place in policy or statute for approximately the last 14 years.

List of Subjects in 32 CFR Part 103

Crime, Health, Military personnel, Reporting and recordkeeping requirements.

■ Accordingly, 32 CFR part 103 is revised to read as follows:

PART 103—SEXUAL ASSAULT PREVENTION AND RESPONSE (SAPR) PROGRAM

Sec.

Authority: 10 U.S.C. 113, and Public Laws 106–65, 108–375, 109–163, 109–364, 110–417, 111–84, 111–383, 112–81, 112–239, 113–291, 113–66,113–291, and 114–92.

§ 103.1 Purpose.

This part is the Department of Defense's comprehensive SAPR program that provides policy guidance and assigns responsibilities for the prevention, response, and oversight of sexual assaults involving members of the U.S. Armed Forces and Reserve Component, to include the National Guard. The SAPR Program is supported by the policies identified in Appendix A to this part.

§ 103.2 Applicability.

(a) This part applies to:

(1) The Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Inspector General of the DoD (IG DoD), the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (hereafter referred to collectively as the ''DoD Components'').

(2) National Guard and Reserve Component members who are sexually assaulted when performing active service, as defined in 10 U.S.C. 101(d)(3), and inactive duty training. Refer to paragraph (c) of Appendix A to this part for information on how to access DoD internal policy containing additional SAPR and healthcare services provided to such personnel and eligibility criteria for Restricted Reporting.

(3) Military dependents 18 years of age and older who are eligible for treatment in the military healthcare system, at installations in the continental United States and outside of the continental United States (OCONUS), and who were victims of sexual assault perpetrated by someone other than a spouse or intimate partner. An adult military dependent may file unrestricted or restricted reports of sexual assault.

(4) The following non-military personnel who are only eligible for limited healthcare (medical and mental health) services in the form of emergency care (see § 103.3), unless otherwise eligible to receive treatment in a military medical treatment facility. They will also be offered the limited SAPR services of a Sexual Assault Response Coordinator (SARC) and a SAPR Victim Advocate (VA) while undergoing emergency care OCONUS. For further information see paragraph (c) of Appendix A to this part. These limited healthcare and SAPR services shall be provided to:

(i) DoD civilian employees and their family dependents 18 years of age and older when they are stationed or performing duties OCONUS and eligible for treatment in the military healthcare system at military installations or facilities OCONUS. For further information see paragraph (c) of Appendix A to this part.

(ii) U.S. citizen DoD contractor personnel when they are authorized to accompany the Armed Forces in a contingency operation OCONUS and their U.S. citizen employees (See 32 CFR part 158 and paragraph (c) of Appendix A to this part).

(5) Service members who are on active duty but were victims of sexual assault prior to enlistment or commissioning. They are eligible to receive full SAPR services and either reporting option.

(b) This part does not apply to victims of sexual assault perpetrated by a spouse or intimate partner, or military dependents under the age of 18 who are sexually assaulted. For further information see paragraph (e) of Appendix A to this part.

(c) This part supersedes all policy and regulatory guidance within the DoD not expressly mandated by law that is inconsistent with its provisions, or that would preclude execution.

§ 103.3 Definitions.

Unless otherwise noted, these terms and their definitions are for the purpose of this part.

Accessions training. Training that a Service member receives upon initial entry into Military Service through basic military training.

Case management group (CMG). A multi-disciplinary group that meets monthly to review individual cases of Unrestricted Reports of sexual assault. The group facilitates monthly victim updates and system coordination, program accountability, and victim access to quality services. At a minimum, each group shall consist of the following additional military or civilian professionals who are involved and working on a specific case: SARC, SAPR VA, military criminal investigator, DoD law enforcement, healthcare provider and mental health and counseling services, chaplain, command legal representative or SJA, and victim's commander.

Certification. Refers to the process by which the Department credentials

SARCs and SAPR VAs, assesses the effectiveness of sexual assault advocacy capabilities using a competencies framework, and evaluates and performs oversight over SARC and SAPR VA training. The certification criteria are established by the Department in consultation with subject-matter experts.

Collateral misconduct. Victim misconduct that might be in time, place, or circumstance associated with the victim's sexual assault incident. Collateral misconduct by the victim of a sexual assault is one of the most significant barriers to reporting assault because of the victim's fear of punishment. Some reported sexual assaults involve circumstances where the victim may have engaged in some form of misconduct (*e.g.,* underage drinking or other related alcohol offenses, adultery, fraternization, or other violations of certain regulations or orders).

Confidential communication. Oral, written, or electronic communications of personally identifiable information (PII) concerning a sexual assault victim and the sexual assault incident provided by the victim to the SARC, SAPR VA, or healthcare personnel in a Restricted Report. This confidential communication includes the victim's SAFE Kit and its information. See *https://www.archives.gov/cui.*

Consent. A freely given agreement to the conduct at issue by a competent person. An expression of lack of consent through words or conduct means there is no consent. Lack of verbal or physical resistance or submission resulting from the use of force, threat of force, or placing another person in fear does not constitute consent. A current or previous dating or social or sexual relationship by itself or the manner of dress of the person involved with the accused in the conduct at issue shall not constitute consent. A sleeping, unconscious, or incompetent person cannot consent.

Credible information. Information that, considering the source and nature of the information and the totality of the circumstances, is sufficiently believable to presume that the fact or facts in question are true.

Credible report. Either a written or verbal report made in support of an Expedited Transfer that is determined to have credible information.

Crisis intervention. Emergency non-clinical care aimed at assisting victims in alleviating potential negative consequences by providing safety assessments and connecting victims to needed resources. Either the SARC or SAPR VA will intervene as quickly as possible to assess the victim's safety and determine the needs of victims and connect them to appropriate referrals, as needed.

Culturally competent care. Care that provides culturally and linguistically appropriate services.

Defense Sexual Assault Incident Database (DSAID). A DoD database that captures uniform data provided by the Military Services and maintains all sexual assault data collected by the Military Services. This database shall be a centralized, case-level database for the uniform collection of data regarding incidence of sexual assaults involving persons covered by this part. DSAID will include information when available, or when not limited by Restricted Reporting, or otherwise prohibited by law, about the nature of the assault, the victim, the offender, and the disposition of reports associated with the assault. DSAID shall be available to the SAPRO and the DoD to develop and implement congressional reporting requirements. Unless authorized by law, or needed for internal DoD review or analysis, disclosure of data stored in DSAID will only be granted when disclosure is ordered by a military, Federal, or State judge or other officials or entities as required by law or applicable U.S. international agreement.

Designated activity. The agency that processes PCS or PCA for Expedited Transfers.

(1) *Air Force:* Air Force Personnel Center.

(2) *Army:* Human Resources Command for inter-installation transfers and the installation personnel center for intra-installation transfers.

(3) *Navy:* Bureau of Naval Personnel.

(4) *U.S. Marine Corps:* The order writing section of Headquarters Marine Corps.

(5) *Air and Army National Guard:* The NGB or the Joint Forces Headquarters-State for the State involved.

Emergency. A situation that requires immediate intervention to prevent the loss of life, limb, sight, or body tissue to prevent undue suffering. Regardless of appearance, a sexual assault victim needs immediate medical intervention to prevent loss of life or undue suffering resulting from internal or external physical injuries, sexually transmitted infections, pregnancy, or psychological distress. Sexual assault victims shall be given priority as emergency cases regardless of evidence of physical injury.

Emergency care. Emergency medical care includes physical and emergency psychological medical services and a SAFE consistent with the most current version of U.S. Department of Justice, Office on Violence Against Women, ''A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents.''

Executive agent. The Head of a DoD Component to whom the Secretary of Defense or the Deputy Secretary of Defense has assigned specific responsibilities, functions, and authorities to provide defined levels of support for operational missions, or administrative or other designated activities that involve two or more of the DoD Components.

FAP. A DoD program designated to address child abuse and domestic abuse in military families in cooperation with civilian social service agencies and military and civilian law enforcement agencies. Prevention, advocacy, and intervention services are provided to individuals who are eligible for treatment in military medical treatment facilities.

Final disposition. Actions taken to resolve the reported incident, document case outcome, and address the misconduct by the alleged perpetrator, as appropriate. It includes, but is not limited to, military justice proceedings, nonjudicial punishment, or administrative actions, including separation actions taken in response to the offense, whichever is the most serious action taken.

Gender-responsive care. Care that acknowledges and is sensitive to gender differences and gender-specific issues.

Healthcare. Medical (physical) and mental healthcare.

Healthcare personnel. Persons assisting or otherwise supporting healthcare providers in providing healthcare services (*e.g.,* administrative personnel assigned to a military MTF). Includes all healthcare providers.

Healthcare provider. Those individuals who are employed or assigned as healthcare professionals or are credentialed to provide healthcare services at an MTF, or who provide such care at a deployed location or otherwise in an official capacity. This also includes military personnel, DoD civilian employees, and DoD contractors who provide healthcare at an occupational health clinic for DoD civilian employees or DoD contractor personnel. Healthcare providers may include, but are not limited to:

(1) Licensed physicians practicing in the MHS with clinical privileges in obstetrics and gynecology, emergency medicine, family practice, internal medicine, pediatrics, urology, general medical officer, undersea medical officer, flight surgeon, psychiatrists, or those having clinical privileges to

perform pelvic examinations or treat mental health conditions.

(2) Licensed advanced practice registered nurses practicing in the MHS with clinical privileges in adult health, family health, midwifery, women's health, mental health, or those having clinical privileges to perform pelvic examinations.

(3) Licensed physician assistants practicing in the MHS with clinical privileges in adult, family, women's health, or those having clinical privileges to perform pelvic examinations.

(4) Licensed registered nurses practicing in the MHS who meet the requirements for performing a SAFE as determined by the local privileging authority. This additional capability shall be noted as a competency, not as a credential or privilege.

(5) A psychologist, social worker, or psychotherapist licensed and privileged to provide mental health care or other counseling services in a DoD or DoD-sponsored facility.

Hospital facilities (Level 3). Minimum operational functions required for a Level 3 hospital include: Command, control, and communications; patient administration; nutritional care; supply and services; triage; emergency medical treatment; preoperative care; orthopedics; general surgery; operating rooms and central materiel and supply services; anesthesia; nursing services (to include intensive and intermediate care wards); pharmacy; clinical laboratory and blood banking; radiology services; and hospital ministry team services.

Intimate partner. A person with whom the victim shares a child in common or with whom the victim shares or has shared a common domicile. For additional information see paragraph (e) of Appendix A to this part.

Installation. A base, camp, post, station, yard, center, homeport facility for any ship, or other activity under the jurisdiction of the Department of Defense, including any leased facility. It does not include any facility used primarily for civil works, rivers and harbors projects, flood control, or other projects not under the primary jurisdiction or control of the Department of Defense. For additional information see paragraph (ii) of Appendix A to this part.

Installation commander. Commander of a base, camp, post, station, yard, center, homeport facility for any ship, or other activity under the jurisdiction of the Department of Defense, including any leased facility. It does not include any facility used primarily for civil works, rivers and harbors projects, flood control, or other projects not under the primary jurisdiction or control of the Department of Defense.

Law enforcement. Includes all DoD law enforcement units, security forces, and MCIOs.

MCIOs. The U.S. Army Criminal Investigation Command, Naval Criminal Investigative Service, and Air Force Office of Special Investigations.

Medical care. Includes physical and psychological medical services.

Military OneSource. A DoD-funded program providing comprehensive information on every aspect of military life at no cost to active duty, National Guard, and Reserve members, and their families. Military OneSource has a mandatory reporting requirement.

Military Services. The term, as used in the SAPR Program, includes Army, Air Force, Navy, Marines, Reserve Components, and their respective Military Academies.

Non-participating victim. Victim choosing not to participate in the military justice system.

Non-identifiable personal information. Non-identifiable personal information includes those facts and circumstances surrounding the sexual assault incident or that information about the individual that enables the identity of the individual to remain anonymous. In contrast, personal identifying information is information belonging to the victim and alleged assailant of a sexual assault that would disclose or have a tendency to disclose the person's identity.

Official investigative process. The formal process a law enforcement organization uses to gather evidence and examine the circumstances surrounding a report of sexual assault.

Open with limited information. Entry in DSAID to be used in the following situations: Victim refused or declined services, victim opt-out of participating in investigative process, third-party reports, local jurisdiction refused to provide victim information, or civilian victim with military subject.

Personal Identifiable Information. Includes the person's name, other particularly identifying descriptions (*e.g.,* physical characteristics or identity by position, rank, or organization), or other information about the person or the facts and circumstances involved that could reasonably be understood to identify the person (*e.g.,* a female in a particular squadron or barracks when there is only one female assigned).

Qualifying conviction. A State or Federal conviction, or a finding of guilty in a juvenile adjudication, for a felony crime of sexual assault and any general or special court-martial conviction for a UCMJ offense, which otherwise meets the elements of a crime of sexual assault, even though not classified as a felony or misdemeanor within the UCMJ. In addition, any offense that requires registration as a sex offender is a qualifying conviction.

Recovery-oriented care. Focus on the victim and on doing what is necessary and appropriate to support victim recovery, and also, if a Service member, to support that Service member to be fully mission capable and engaged.

Responders. Includes first responders, who are generally composed of personnel in the following disciplines or positions: SARCs, SAPR VAs, healthcare personnel, law enforcement, and MCIOs. Other responders are judge advocates, chaplains, and commanders, but they are usually not first responders.

Respond, response, or response capability. All locations, including deployed areas, have a 24 hour, 7 days per week, sexual assault response capability. The SARC shall be notified, respond, or direct a SAPR VA to respond, assign a SAPR VA, and offer the victim healthcare treatment and a SAFE. In geographic locations where there is no SARC onsite, the on-call SAPR VA shall respond, offer the victim healthcare treatment and a SAFE, and immediately notify the SARC of the sexual assault. The initial response is generally composed of personnel in the following disciplines or positions: SARCs, SAPR VAs, healthcare personnel, law enforcement, and MCIOs. Other responders are judge advocates, chaplains, and commanders. When victims geographically detached from a military installation, the SARC or SAPR VA will refer to local civilian providers or the DoD Safe Helpline for resources.

Restricted Reporting. Reporting option that allows sexual assault victims to confidentially disclose the assault to specified individuals (*i.e.,* SARC, SAPR VA, or healthcare personnel), and receive medical treatment, including emergency care, counseling, and assignment of a SARC and SAPR VA, without triggering an investigation. The victim's report provided to healthcare personnel (including the information acquired from a SAFE Kit), SARCs, or SAPR VAs will NOT be reported to law enforcement or to the command to initiate the official investigative process unless the victim consents or an established exception applies. The Restricted Reporting Program applies to Service members and their military dependents 18 years of age and older. Additional persons who may be entitled to Restricted Reporting are NG and Reserve members. DoD civilians and

contractors are only eligible to file an Unrestricted Report. Only a SARC, SAPR VA, or healthcare personnel may receive a Restricted Report, previously referred to as Confidential Reporting.

Re-victimization. A pattern wherein the victim of abuse or crime has a statistically higher tendency to be victimized again, either shortly thereafter or much later in adulthood in the case of abuse as a child. This latter pattern is particularly notable in cases of sexual abuse.

Safe Helpline. A crisis support service for members of the DoD community affected by sexual assault. The DoD Safe Helpline is available 24/7 worldwide with ''click, call, or text'' user options for anonymous and confidential support; can be accessed by logging on to *www.safehelpline.org* or by calling 1–877–995–5247, and through the Safe Helpline mobile application; is to be utilized as the sole DoD hotline. However, the local base and installation SARC or SAPR VA contact information is not replaced.

Safety assessment. A set of guidelines and considerations post-sexual assault that the responsible personnel designated by the Installation Commander can follow to determine if a sexual assault survivor is likely to be in imminent danger of physical or psychological harm as a result of being victimized by or reporting sexual assault(s). The guidelines and considerations consist of a sequence of questions, decisions, referrals, and actions that responders can enact to contribute to the safety of survivors during the first 72 hours after a report, and during other events that can increase the lethality risk for survivors (*e.g.,* arrests or command actions against the alleged perpetrators). Types of imminent danger may include non-lethal, lethal, or potentially lethal behaviors; the potential harm caused by the alleged perpetrator, family/friend(s)/acquaintance(s) of the alleged perpetrator, or the survivors themselves (*e.g.,* harboring self-harm or suicidal thoughts). The safety assessment includes questions about multiple environments, to include home and the workplace. Survivors are assessed for their perception or experience of potential danger from their leadership or peers via reprisal or ostracism. The safety assessment contains a safety plan component that survivors can complete and take with them to help improve coping, social support, and resource access during their recovery period.

SAPR Integrated Product Team (IPT). A team of individuals that advises the USD(P&R) and the Secretary of Defense on policies for sexual assault issues. The SAPR IPT serves as the implementation and oversight arm of the SAPR Program. It coordinates policy and reviews the DoD's SAPR policies and programs and monitors the progress of program elements. For additional information see paragraph (c) of Appendix A to this part.

SAFE Kit. The medical and forensic examination of a sexual assault victim under circumstances and controlled procedures to ensure the physical examination process and the collection, handling, analysis, testing, and safekeeping of any bodily specimens and evidence meet the requirements necessary for use as evidence in criminal proceedings. The victim's SAFE Kit is treated as a confidential communication when conducted as part of a Restricted Report.

SAPRO. Serves as the DoD's single point of authority, accountability, and oversight for the SAPR program, except for legal processes and criminal investigative matters that are the responsibility of the Judge Advocates General of the Military Departments and the IG, respectively.

SAPR Program. A DoD program for the Military Departments and the DoD Components that establishes SAPR policies to be implemented worldwide. The program objective is an environment and military community intolerant of sexual assault.

SAPR VA. A person who, as a victim advocate, shall provide non-clinical crisis intervention, referral, and ongoing non-clinical support to adult sexual assault victims. Support will include providing information on available options and resources to victims. The SAPR VA, on behalf of the sexual assault victim, provides liaison assistance with other organizations and agencies on victim care matters and reports directly to the SARC when performing victim advocacy duties. Personnel who are interested in serving as a SAPR VA are encouraged to volunteer for this duty assignment.

SARC. The single point of contact at an installation or within a geographic area who oversees sexual assault awareness, prevention, and response training; coordinates medical treatment, including emergency care, for victims of sexual assault; and tracks the services provided to a victim of sexual assault from the initial report through final disposition and resolution.

Secondary victimization. The re-traumatization of the sexual assault, abuse, or rape victim. It is an indirect result of assault that occurs through the responses of individuals and institutions to the victim. The types of secondary victimization include victim blaming, inappropriate behavior or language by medical personnel and by other organizations with access to the victim post assault.

Senior commander. An officer, usually in the grade of O–6 or higher, who is the commander of a military installation or comparable unit and has been designated by the Military Service concerned to oversee the SAPR Program.

Service member. An active duty member of a Military Service. In addition, National Guard and Reserve Component members who are sexually assaulted when performing active service, as defined in 10 U.S.C. 101(d)(3), and inactive duty training.

Sexual assault. Intentional sexual contact characterized by use of force, threats, intimidation, or abuse of authority or when the victim does not or cannot consent. The term includes a broad category of sexual offenses consisting of the following specific UCMJ offenses: Rape, sexual assault, aggravated sexual contact, abusive sexual contact, forcible sodomy (forced oral or anal sex), or attempts to commit these acts.

SVC. Attorneys who are assigned to provide legal services in accordance with section 1716 of Public Law 113–66 and Service regulations. The Air Force, Army, National Guard, and Coast Guard refer to these attorneys as SVC. The Navy and Marine Corps refer to these attorneys as VLC.

SVIP capability. A distinct, recognizable group of appropriately skilled professionals, including MCIO investigators, judge advocates, victim witness assistance personnel, and administrative paralegal support personnel, who work collaboratively to:

(1) Investigate and prosecute allegations of child abuse (involving sexual assault or aggravated assault with grievous bodily harm), domestic violence (involving sexual assault or aggravated assault with grievous bodily harm), and adult sexual assault (not involving domestic offenses)

(2) Provide support for the victims of such offenses. For additional information see paragraph (bb) of Appendix A to this part.

Trauma informed care. An approach to engage people with histories of trauma that recognizes the presence of trauma symptoms and acknowledges the role that trauma has played in their lives. Trauma-informed services are based on an understanding of the vulnerabilities or triggers of trauma survivors that traditional service delivery approaches may exacerbate, so that these services and programs can be

more supportive and avoid re-traumatization.

Victim. A person who asserts direct physical, emotional, or pecuniary harm as a result of the commission of a sexual assault. The term encompasses all persons 18 and over eligible to receive treatment in military medical treatment facilities.

VLC. Attorneys who are assigned to provide legal services in accordance with section 1716 of Public Law 113–66, ''The National Defense Authorization Act for Fiscal Year 2014,'' and Service regulations. The Air Force, Army, National Guard, and Coast Guard refer to these attorneys as SVC. The Navy and Marine Corps refer to these attorneys as VLC.

VWAP. Provides guidance for assisting victims and witnesses of crime from initial contact through investigation, prosecution, and confinement. Particular attention is paid to victims of serious and violent crime, including child abuse, domestic violence, and sexual misconduct. For additional information see paragraph (aa) of Appendix A to this part.

§ 103.4 Policy.

(a) This part implements the DoD SAPR policy and the DoD SAPR Program Unrestricted and Restricted Reporting options are available to Service members and their adult military dependents. For further information see paragraph (c) of Appendix A to this part.

(b) The DoD SAPR Program focuses on prevention, education and training, response capability (defined in § 103.3), victim support, reporting procedures, and appropriate accountability.

(c) While a sexual assault victim may disclose information to whomever he or she chooses, an official report is made only when a DD Form 2910 is signed and filed with a SARC or SAPR VA, or when a Military Criminal Investigative Organization (MCIO) investigator initiates an investigation.

(d) For Restricted and Unrestricted Reporting purposes, a report can be made to healthcare personnel, but healthcare personnel then immediately contact the SARC or SAPR VA to fill out the DD Form 2910.

(e) State laws or regulations that require disclosure of PII of the adult sexual assault victim or alleged perpetrator to local or State law enforcement shall not apply, except when reporting is necessary to prevent or mitigate a serious and imminent threat to the health or safety of an individual.

(f) Unless a DD Form 2910 is filed with a SARC, a report to a Chaplain or military attorney may not result in the rendering of SAPR services or investigative action because of the privileges associated with speaking to these individuals. A Chaplain or military attorney should advise the victim to consult with a SARC to understand the full scope of services available or facilitate, with the victim's consent, contact with a SARC.

(g) The SAPR Program shall:

(1) Focus on the victim and on doing what is necessary and appropriate to support victim recovery, and also, if a Service member, to support that Service member to be fully mission capable and engaged. The SAPR Program shall provide care that is gender-responsive, culturally competent, and recovery-oriented. For further information see paragraph (c) of Appendix A to this part.

(2) Not provide policy for legal processes within the responsibility of the Judge Advocates General of the Military Departments provided in 10 U.S.C. chapter 47 and the Manual for Courts-Martial or for criminal investigative matters assigned to the IG DoD.

(h) Standardized SAPR requirements, terminology, guidelines, protocols, and guidelines for instructional materials shall focus on awareness, prevention, and response at all levels as appropriate.

(i) The terms ''Sexual Assault Response Coordinator (SARC)'' and ''SAPR Victim Advocate (VA),'' as defined in § 103.3, shall be used as standard terms throughout the DoD to facilitate communications and transparency regarding SAPR capacity. For further information regarding SARC and SAPR VA roles and responsibilities, see paragraph (c) of Appendix A to this part.

(1) *SARC.* The SARC shall serve as the single point of contact for coordinating appropriate and responsive care for sexual assault victims. SARCs shall coordinate sexual assault victim care and sexual assault response when a sexual assault is reported. The SARC shall supervise SAPR VAs but may be called on to perform victim advocacy duties.

(2) *SAPR VA.* The SAPR VA shall provide non-clinical crisis intervention and on-going support, in addition to referrals for adult sexual assault victims. Support will include providing information on available options and resources to victims.

(j) An immediate, trained sexual assault response capability shall be available for each report of sexual assault in all locations, including in deployed locations. The response time may be affected by operational necessities but will reflect that sexual assault victims shall be treated as emergency cases. For further information see paragraph (c) of Appendix A to this part.

(k) Victims of sexual assault shall be protected from coercion, retaliation, and reprisal. For additional information see paragraph (g) of Appendix A to this part.

(l) Victims of sexual assault shall be protected, treated with dignity and respect, and shall receive timely access to comprehensive healthcare (medical and mental health) treatment, including emergency care treatment and services. For additional information see paragraph (c) of Appendix A to this part.

(m) Emergency care for victims of sexual assault shall consist of emergency healthcare and the offer of a sexual assault forensic examination (SAFE). For additional information see paragraph (h) of Appendix A to this part.

(1) Sexual assault patients shall be given priority and shall be treated as emergency cases. A sexual assault victim needs immediate medical intervention to prevent loss of life or suffering resulting from physical injuries (internal or external), sexually transmitted infections, pregnancy, and psychological distress. Individuals disclosing a recent sexual assault shall, with their consent, be quickly transported to the exam site, promptly evaluated, treated for serious injuries, and then, with the patient's consent, undergo a SAFE. For additional information see paragraph (ff) of Appendix A to this part.

(2) Sexual assault patients shall be treated as emergency cases, regardless of whether physical injuries are evident. Patients' needs shall be assessed for immediate medical or mental health intervention. Sexual assault victims shall be treated uniformly regardless of their behavior because when severely traumatized, sexual assault patients may appear to be calm, indifferent, submissive, jocular, angry, emotionally distraught, or even uncooperative or hostile towards those who are trying to help. For additional information see paragraph (h) of Appendix A to this part.

(n) There will be a safety assessment capability for the purposes of ensuring the victim, and possibly other persons, are not in physical jeopardy. A safety assessment will be available to all Service members, adult military dependents, and civilians who are eligible for SAPR services, even if the victim is not physically located on the installation. The installation

commander or the deputy installation commander will identify installation personnel who have been trained and are able to perform a safety assessment of each sexual assault victim, regardless of whether he or she filed a Restricted or Unrestricted Report. Individuals tasked to conduct safety assessments must occupy positions that do not compromise the victim's reporting options. The safety assessment will be conducted as soon as possible, understanding that any delay may impact the safety of the victim.

(o) Service members and their dependents who are 18 years of age or older covered by this part who are sexually assaulted have two reporting options: Unrestricted or Restricted Reporting. Unrestricted Reporting of sexual assault is favored by the DoD. For additional information see paragraph (c) of Appendix A to this part. Protections are taken with PII solicited, collected, maintained, accessed, used, disclosed, and disposed during the treatment and reporting processes. For additional information see paragraph (j) of Appendix A to this part. The two reporting options are as follows:

(1) Unrestricted Reporting allows an eligible person who is sexually assaulted to access healthcare and counseling and request an official investigation of the allegation using existing reporting channels (*e.g.,* chain of command, law enforcement, healthcare personnel, the SARC). When a sexual assault is reported through Unrestricted Reporting, a SARC shall be notified as soon as possible, respond, assign a SAPR VA, and offer the victim healthcare and a SAFE.

(2) Restricted Reporting allows sexual assault victims to confidentially disclose the assault to specified individuals (*i.e.,* SARC, SAPR VA, or healthcare personnel), in accordance with this part, and receive healthcare treatment, including emergency care, counseling, and assignment of a SARC and SAPR VA, without triggering an official investigation. The victim's report to healthcare personnel (including the information acquired from a SAFE Kit), SARCs, or SAPR VAs will not be reported to law enforcement or to the victim's command, to initiate the official investigative process, unless the victim consents or an established exception exists in State laws or federal regulations. When a sexual assault is reported through Restricted Reporting, a SARC shall be notified as soon as possible, respond, assign a SAPR VA, and offer the victim healthcare and a SAFE. For additional information see paragraph (c) of Appendix A to this part).

(i) *Eligibility for Restricted Reporting.* The Restricted Reporting option applies to Service members and their military dependents 18 years of age and older. For additional information, see paragraph (c) of Appendix A to this part.

(ii) *DoD dual objectives.* The DoD is committed to ensuring victims of sexual assault are protected; treated with dignity and respect; and provided support, advocacy, and care. The DoD also strongly supports applicable law enforcement and criminal justice procedures that enable persons to be held accountable for sexual assault offenses and criminal dispositions, as appropriate. To achieve these dual objectives, DoD preference is for Unrestricted Reporting of sexual assaults to allow for the provision of victims' services and to pursue accountability. However, Unrestricted Reporting may represent a barrier for victims to access services, when the victim desires no command or law enforcement involvement. Consequently, the DoD recognizes a fundamental need to provide a confidential disclosure vehicle via the Restricted Reporting option.

(iii) *Designated personnel authorized to accept a Restricted Report.* Only the SARC, SAPR VA, or healthcare personnel are designated as authorized to accept a Restricted Report.

(iv) *SAFE confidentiality under Restricted Reporting.* A SAFE and its information shall be afforded the same confidentiality as is afforded victim statements under the Restricted Reporting option. See paragraph (c) of Appendix A to this part for additional information.

(v) *Disclosure of confidential communications.* In cases where a victim elects Restricted Reporting, the SARC, assigned SAPR VA, and healthcare personnel may not disclose confidential communications or SAFE Kit information to law enforcement or command authorities, either within or outside the DoD. In certain situations when information about a sexual assault comes to the commander's or law enforcement official's attention from a source independent of the Restricted Reporting avenues and an independent investigation is initiated, a SARC, SAPR VA, or healthcare personnel may not disclose confidential communications if obtained under Restricted Reporting. Improper disclosure of confidential communications protected under Restricted Reporting, improper release of healthcare information, and other violations of this policy or other laws and regulations are prohibited and may result in discipline pursuant to the UCMJ, or other adverse personnel or administrative actions. See paragraph (c) of Appendix A to this part for additional information.

(p) Eligible victims must be informed of the availability of legal assistance and the right to consult with an SVC/VLC in accordance with section 1716 of the NDAA for Fiscal Year (FY) 2014 (Pub. L. 113–66).

(q) Enlistment or commissioning of personnel in the Military Services shall be prohibited and no waivers are allowed when the person has a qualifying conviction (see § 103.3) for a crime of sexual assault.

(r) The DoD shall provide support to an active duty Service member regardless of when or where the sexual assault took place.

(s) Information regarding Unrestricted Reports should only be released to personnel with an official need to know or as authorized by law. Improper disclosure of confidential communications under Unrestricted Reporting or improper release of medical information are prohibited and may result in disciplinary action pursuant to the UCMJ or other adverse personnel or administrative actions.

(t) The DoD will retain the DD Forms 2910, ''Victim Reporting Preference Statement,'' and 2911, ''DoD Sexual Assault Forensic Examination (SAFE) Report,'' for 50 years, regardless of whether the Service member filed a Restricted or Unrestricted Report as defined in this part. PII will be protected in accordance with 5 U.S.C. 552a, also known as the Privacy Act of 1974 (5 U.S.C. 552a) and 32 CFR part 310 and Public Law 104–191.

(u) For document retention and SAFE Kit retention for Unrestricted Reports:

(1) The SARC will enter the Unrestricted Report DD Form 2910 in the DSAID (see § 103.3) as an electronic record within 48 hours of the report, where it will be retained for 50 years from the date the victim signed the DD Form 2910. The DD Form 2910 is located at the DoD Forms Management Program website at *https://www.esd.whs.mil/Directives/forms/.*

(2) The DD Form 2911 shall be retained in accordance with the Department's internal policies. For further information, see paragraph (n) of Appendix A to this part. The DD Form 2911 is located at the DoD Forms Management Program website at *https://www.esd.whs.mil/Directives/forms/.*

(3) If the victim had a SAFE, the SAFE Kit will be retained for 5 years in accordance with section 586 of Public Law 112–81, as amended by section 538 of Public Law 113–291. For further information see paragraph (n) of

Appendix A to this part. When the forensic examination is conducted at a civilian facility through a memorandum of understanding (MOU) or a memorandum of agreement (MOA) with the DoD, the requirement for the handling of the forensic kit will be explicitly addressed in the MOU or MOA. The MOU or MOA with the civilian facility will address the processes for contacting the SARC and for contacting the appropriate DoD agency responsible for accepting custody of the SAFE.

(4) Personal property retained as evidence collected in association with a sexual assault investigation will be retained for a period of 5 years. Personal property may be returned to the rightful owner of such property after the conclusion of all legal, adverse action and administrative proceedings related to such incidents in accordance with section 586 of the NDAA for FY 2012, as amended by section 538 of Public Law 113–291 and DoD regulations.

(v) For document retention and SAFE Kit retention for Restricted Reports:

(1) The SARC will retain a copy of the Restricted Report DD Form 2910 for 50 years, consistent with DoD guidance for the storage of PII. The 50-year time frame for the DD Form 2910 will start from the date the victim signs the DD Form 2910. For Restricted Reports, forms will be retained in a manner that protects confidentiality.

(2) If the victim had a SAFE, the Restricted Report DD Form 2911 will be retained for 50 years, consistent with DoD guidance for the storage of PII. The 50-year time frame for the DD Form 2911 will start from the date the victim signs the DD Form 2910, but if there is no DD Form 2910, the timeframe will start from the date the SAFE Kit is completed. Restricted Report forms will be retained in a manner that protects confidentiality.

(3) If the victim had a SAFE, the SAFE Kit will be retained for 5 years in a location designated by the Military Service concerned. When the forensic examination is conducted at a civilian facility through an MOU or a MOA with the DoD, the requirement for the handling of the forensic kit will be explicitly addressed in the MOU or MOA. The MOU or MOA with the civilian facility will address the processes for contacting the SARC and for contacting the appropriate DoD agency responsible for accepting custody of the forensic kit. The 5-year time frame will start from the date the victim signs the DD Form 2910, but if there is no DD Form 2910, the timeframe will start from the date the SAFE Kit is completed.

(4) Personal property retained as evidence collected in association with a sexual assault investigation will be retained for a period of 5 years. In the event the report is converted to Unrestricted or an independent investigation is conducted, personal property may be returned to the rightful owner of such property after the conclusion of all legal, adverse action and administrative proceedings related to such incidents in accordance with section 586 of Public Law 112–81, as amended by section 538 of Public Law 113–291, and DoD regulations. However, victims who filed a Restricted Report may request the return of personal property obtained as part of the sexual assault forensic examination at any time in accordance with section 536 of Public Law 116–92, and DoD regulations.

§ 103.5 Responsibilities.

(a) In accordance with the authority in DoD policy (see paragraph (t) of Appendix A to this part), the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) shall:

(1) Develop overall policy and provide oversight for the DoD SAPR Program, except legal processes in the UCMJ and criminal investigative matters assigned to the Judge Advocates General of the Military Departments, the Staff Judge Advocate to the Commandant of the Marine Corps, and IG DoD, respectively.

(2) Develop strategic program guidance, joint planning objectives, standard terminology, and identify legislative changes needed to ensure the future availability of resources in support of DoD SAPR policies.

(3) Develop metrics to measure compliance and effectiveness of SAPR training, awareness, prevention, and response policies and programs. Analyze data and make recommendations regarding the SAPR policies and programs to the Secretaries of the Military Departments.

(4) Monitor compliance with this part and internal policy (see paragraph (c) of Appendix A to this part), and coordinate with the Secretaries of the Military Departments regarding Service SAPR policies.

(5) Collaborate with Federal and State agencies that address SAPR issues and serve as liaison to them as appropriate. Strengthen collaboration on sexual assault policy matters with U.S. Department of Veterans Affairs on the issues of providing high quality and accessible health care and benefits to victims of sexual assault.

(6) Oversee the DoD Sexual Assault Prevention and Response Office (SAPRO). Serving as the DoD single point of authority, accountability, and oversight for the SAPR program, SAPRO provides recommendations to the USD(P&R) on the issue of DoD sexual assault policy matters on prevention, response, and oversight. The SAPRO Director will be appointed from among general or flag officers of the Military Services or DoD employees in a comparable Senior Executive Service position in accordance with Public Law 112–81, ''National Defense Authorization Act for Fiscal Year 2012.'' The SAPRO Director is responsible for:

(i) Implementing and monitoring compliance with DoD sexual assault policy on prevention and response, except for legal processes in accordance with paragraph (kk) of Appendix A to this part and Public Law 114–92, ''National Defense Authorization Act for Fiscal Year 2016,'' and criminal investigative matters assigned to the Judge Advocates General of the Military Departments, the Staff Judge Advocate to the Commandant of the Marine Corps, and IG DoD, respectively.

(ii) Providing technical assistance to the Heads of the DoD Components in addressing matters concerning SAPR.

(iii) Acquiring quarterly and annual SAPR data from the Military Services, assembling annual congressional reports involving persons covered by this part and DoD Instruction 6495.02, and consulting with and relying on the Judge Advocates General of the Military Departments and the Staff Judge Advocate to the Commandant of the Marine Corps in questions concerning disposition results of sexual assault cases in their respective Departments.

(iv) Establishing reporting categories and monitoring specific goals included in the annual SAPR assessments of each Military Service, in their respective Departments.

(v) Overseeing the creation, implementation, maintenance, and function of the DSAID, an integrated database that will meet congressional reporting requirements, support Service SAPR Program management, and inform DoD SAPRO oversight activities.

(vi) Overseeing development of strategic program guidance and joint planning objectives for resources in support of the SAPR Program, and making recommendations on modifications to policy, law, and regulations needed to ensure the continuing availability of such resources (Pub. L. 113–66).

(b) The Assistant Secretary of Defense for Health Affairs (ASD(HA)), under the authority, direction, and control of the USD(P&R), shall advise the USD(P&R) on DoD sexual assault healthcare

policies, clinical practice guidelines, related procedures, and standards governing DoD healthcare programs for victims of sexual assault. The ASD(HA) shall:

(1) Direct that all sexual assault patients be given priority, so that they shall be treated as emergency cases.

(2) Require standardized, timely, accessible, and comprehensive medical care at MTFs for eligible persons who are sexually assaulted.

(3) Require that medical care be consistent with established community standards for the healthcare of sexual assault victims and the collection of forensic evidence from victims. For further information see paragraphs (h) and (ff) of Appendix A to this part.

(4) Establish guidance for medical personnel that requires a SARC or SAPR VA to be called in for every incident of sexual assault for which treatment is sought at the MTFs, regardless of the reporting option.

(c) The Director of Department of Defense Human Resources Activity (DoDHRA), under the authority, direction, and control of USD(P&R), shall provide operational support to the USD(P&R) as outlined in paragraph (a)(6) of this section.

(d) The General Counsel of the DoD (GC DoD) shall provide legal advice and assistance on all legal matters, including the review and coordination of all proposed issuances and exceptions to policy and the review of all legislative proposals, affecting mission and responsibilities of the DoD SAPRO.

(e) The Inspector General of the Department of Defense (IG DoD) shall:

(1) Develop and oversee the promulgation of criminal investigative and law enforcement policy regarding sexual assault and establish guidelines for the collection and preservation of evidence with non-identifiable personal information on the victim, for the Restricted Reporting process, in coordination with the ASD(HA).

(2) Oversee criminal investigations of sexual assault conducted by the DoD Components.

(3) Collaborate with the DoD SAPRO in the development of investigative policy in support of sexual assault prevention and response.

(f) The Secretaries of the Military Departments shall:

(1) Establish departmental policies and procedures to implement the SAPR Program consistent with the provisions of this part to include the military academies within their cognizance; monitor departmental compliance with this part and DoD internal policy. For further information see paragraph (c) of Appendix A to this part.

(2) Coordinate all Military Service SAPR policy changes with the USD(P&R).

(3) In coordination with the USD(P&R), implement recommendations regarding Military Service compliance and effectiveness of SAPR training, awareness, prevention, and response policies and programs.

(4) Align Service SAPR strategic plans with the DoD SAPR Strategic Plan.

(5) Align Service prevention strategies with the DoD Sexual Assault Prevention Strategy.

(6) Utilize the terms ''Sexual Assault Response Coordinator (SARC)'' and ''SAPR Victim Advocate (VA),'' as defined in this part as standard terms to facilitate communications and transparency regarding sexual assault response capacity.

(7) Establish the position of the SARC to serve as the SINGLE POINT OF CONTACT for ensuring that sexual assault victims receive appropriate and responsive care. The SARC should be a Service member, DoD civilian employee, or National Guard technician.

(8) Direct that the SARC or a SAPR VA be immediately called in every incident of sexual assault on a military installation. There will be situations where a sexual assault victim receives medical care and a SAFE outside of a military installation through an MOU or MOA with a local private or public sector entity. In these cases, the MOU or MOA will require that a SARC be notified as part of the MOU or MOA.

(9) Sexual assault victims shall be offered the assistance of a SARC and/or SAPR VA who has been credentialed by the D–SAACP. For further information see paragraph (w) of Appendix A to this part.

(10) Establish and codify Service SAPR Program support to Combatant Commands and Defense Agencies, either as a host activity or in a deployed environment.

(11) Provide SAPR Program and obligation data to the USD(P&R), as required.

(12) Submit required data to DSAID. Require confirmation that a multi-disciplinary CMG tracks each open Unrestricted Report, is chaired by the installation commander (or the deputy installation commander), and that CMG meetings are held monthly for reviewing all Unrestricted Reports of sexual assaults. For further information see paragraph (c) of Appendix A to this part.

(13) Provide annual reports of sexual assaults involving persons covered by this part and DoD Instruction 6495.02 to the DoD SAPRO for consolidation into the annual report to Congress in accordance with section 577 of Public Law 108–375.

(14) Provide data connectivity, or other means, to authorized users to ensure all sexual assaults reported in theater and other joint environments are incorporated into the DSAID, or authorized interfacing systems for the documentation of reports of sexual assault, as required by section 563 of Public Law 110–417.

(15) Ensure that Service data systems used to report case-level sexual assault information into the DSAID are compliant with DoD data reporting requirements, pursuant to section 563 of Public Law 110–417.

(16) Require extensive, continuing in-depth SAPR training for DoD personnel and specialized SAPR training for commanders, senior enlisted leaders, SARCs, SAPR VAs, investigators, law enforcement officials, chaplains, healthcare personnel, and legal personnel. For further information see paragraph (c) of Appendix A to this part.

(17) Require the installation SARC and the installation FAP staff to coordinate together when a sexual assault occurs as a result of domestic abuse or domestic violence or involves child abuse to ensure the victim is directed to FAP.

(18) Oversee sexual assault training within the DoD law enforcement community.

(19) Direct that Service military criminal investigative organizations require their investigative units to communicate with their servicing SARC and participate with the multi-disciplinary CMG. For further information see paragraph (c) of Appendix A to this part.

(20) Establish procedures to ensure that, in the case of a general or special court-martial the trial counsel causes each qualifying victim to be notified of the opportunity to receive a copy of the record of trial (not to include sealed materials, unless approved by the presiding military judge or appellate court, classified information, or other portions of the record the release of which would unlawfully violate the privacy interests of any party, and without a requirement to include matters attached to the record under Rule for Courts-Martial (R.C.M.) 1103(b)(3) in U.S. Department of Defense, ''Manual for Courts-Martial, United States''). A qualifying alleged victim is an individual named in a specification alleging an offense under Articles 120, 120b, 120c, or 125 of the UCMJ (10 U.S.C. 920, 920b, 920c, or 925), or any attempt to commit such offense in violation of Article 80 of the

UCMJ (10 U.S.C. 880), if the court-martial resulted in any finding to that specification. If the alleged victim elects to receive a copy of the record of proceedings, it shall be provided without charge and within a timeframe designated by regulations of the Military Department concerned. The victim shall be notified of the opportunity to receive the record of the proceedings in accordance with R.C.M. 1103(g)(3)(C) in U.S. Department of Defense, ''Manual for Courts-Martial, United States''.

(21) Require that a completed DD Form 2701, ''Initial Information for Victims and Witnesses of Crime,'' be distributed to the victim. (DD Form 2701 is located at the DoD Forms Management Program website at *https://www.esd.whs.mil/Directives/forms/* and in DoD Instruction 1030.2). For further information see paragraph (n) of Appendix A to this part.

(22) When drafting MOUs or MOAs with local civilian medical facilities to provide DoD-reimbursable healthcare (to include psychological care) and forensic examinations for Service members and TRICARE eligible sexual assault victims, require commanders to include the following provisions:

(i) Local private or public sector providers notify the SARC or SAPR VA.

(ii) Local private or public sector providers shall have processes and procedures in place to assess that local community standards meet or exceed those set forth in U.S. Department of Justice, Office on Violence Against Women, ''A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents,'' current version as a condition of the MOUs or MOAs.

(23) Comply with collective bargaining obligations, if applicable.

(24) Provide SAPR training and education for civilian employees of the military departments in accordance with section 585 of Public Law 112–81.

(25) Require the SARCs and SAPR VAs to collaborate with designated Special Victim Investigation and Prosecution (SVIP) Capability personnel during all stages of the investigative and military justice process to ensure an integrated capability to the greatest extent possible. For further information see paragraphs (bb) and (cc) of Appendix A to this part.

§ 103.6 Reporting options and sexual assault reporting procedures.

(a) *Reporting options.* Service members and military dependents 18 years and older who have been sexually assaulted have two reporting options: Unrestricted or Restricted Reporting. Unrestricted Reporting of sexual assault is favored by the DoD. However, Unrestricted Reporting may represent a barrier for victims to access services, when the victim desires no command or DoD law enforcement involvement. Consequently, the DoD recognizes a fundamental need to provide a confidential disclosure vehicle via the Restricted Reporting option. Regardless of whether the victim elects Restricted or Unrestricted Reporting, DoD shall maintain confidentiality of medical information. For further information see paragraph (j) of Appendix A to this part. DoD civilian employees and their family dependents and DoD contractors are only eligible for Unrestricted Reporting and for limited emergency care medical services at an MTF, unless that individual is otherwise eligible as a Service member or TRICARE beneficiary of the military health system to receive treatment in an MTF at no cost to them in accordance with this part.

(1) *Unrestricted reporting.* This reporting option triggers an investigation, command notification, and allows a person who has been sexually assaulted to access healthcare treatment and the assignment of a SARC and a SAPR VA. When a sexual assault is reported through Unrestricted Reporting, a SARC shall be notified, respond or direct a SAPR VA to respond, offer the victim healthcare treatment and a SAFE, and inform the victim of available resources. The SARC or SAPR VA will explain the contents of the DD Form 2910 and request that the victim elect a reporting option on the form. If the victim elects the Unrestricted Reporting option, a victim may not change from an Unrestricted to a Restricted Report. If the Unrestricted option is elected, the completed DD Form 2701, which sets out victims' rights and points of contact, shall be distributed to the victim in Unrestricted Reporting cases by DoD law enforcement agents. If a victim elects this reporting option, a victim may not change from an Unrestricted to a Restricted Report.

(2) *Restricted Reporting.* This reporting option does not trigger an investigation. The command is notified that ''an alleged sexual assault'' occurred but is not given the victim's name or other personally identifying information. Restricted Reporting allows Service members and military dependents who are adult sexual assault victims to confidentially disclose the assault to specified individuals (SARC, SAPR VA, or healthcare personnel) and receive healthcare treatment and the assignment of a SARC and SAPR VA. A sexual assault victim can report directly to a SARC, who will respond or direct a SAPR VA to respond, offer the victim healthcare treatment and a SAFE, and explain to the victim the resources available through the DD Form 2910, where the reporting option is elected. The Restricted Reporting option is only available to Service members and adult military dependents. Restricted Reporting may not be available in a jurisdiction that requires mandatory reporting if a victim first reports to a civilian facility or civilian authority, which will vary by state, territory, and overseas agreements. See paragraph (c) of Appendix A to this part for additional information. However, section 536 of the NDAA for FY 2016 preempts mandatory reporting laws, provided the victim first reports to an MTF, except when reporting is necessary to prevent or mitigate a serious and imminent threat to the health or safety of an individual, thereby preserving the Restricted Reporting option. If a victim elects this reporting option, a victim may convert a Restricted Report to an Unrestricted Report at any time. The conversion to an Unrestricted Report will be documented with a signature by the victim and the signature of the SARC or SAPR VA in the appropriate block on the DD Form 2910.

(i) Only the SARC, SAPR VA, and healthcare personnel are designated as authorized to accept a Restricted Report. Healthcare personnel, to include psychotherapists and other personnel listed in Military Rule of Evidence (MRE) 513 of Office of the Chairman of the Joint Chiefs of Staff, ''DoD Dictionary of Military and Associated Terms,'' who received a Restricted Report (meaning that a victim wishes to file a DD Form 2910 or have a SAFE) shall contact a SARC or SAPR VA. For further information see paragraph (c) of Appendix A to this part.

(ii) A SAFE and the information contained in its accompanying Kit are provided the same confidentiality as is afforded victim statements under the Restricted Reporting option. For further information see paragraph (c) of Appendix A to this part.

(iii) The victim's decision not to participate in an investigation or prosecution will not affect access to SARC and SAPR VA services, medical and psychological care, or services from an SVC or VLC. These services shall be made available to all eligible sexual assault victims.

(iv) If a victim approaches a SARC, SAPR VA, or healthcare provider and begins to make a report, but then changes his or her mind and leaves without signing the DD Form 2910 (the form where the reporting option is selected), the SARC, SAPR VA, or

healthcare provider is not under any obligation or duty to inform investigators or commanders about this report and will not produce the report or disclose the communications surrounding the report.

(b) *Disclosure of confidential communications.* In cases where a victim elects Restricted Reporting, the SARC, SAPR VA, and healthcare personnel may not disclose confidential communications or the SAFE and the accompanying Kit to DoD law enforcement or command authorities, either within or outside the DoD. In certain situations, information about a sexual assault may come to the commander's or DoD law enforcement official's (to include MCIO's) attention from a source independent of the Restricted Reporting avenues and an independent investigation is initiated. In these cases, SARCs, SAPR VAs, and healthcare personnel are prevented from disclosing confidential communications under Restricted Reporting, unless an exception applies. An independent investigation does not, in itself, convert the Restricted Report to an Unrestricted Report. For further information see paragraph (c) of Appendix A to this part.

(c) *Independent investigations.* Independent investigations are not initiated by the victim. If information about a sexual assault comes to a commander's attention from a source other than a victim (victim may have elected Restricted Reporting or where no report has been made by the victim), that commander shall immediately report the matter to an MCIO and an official (independent) investigation may be initiated based on that independently acquired information.

(1) If there is an ongoing independent investigation, the sexual assault victim will no longer have the option of Restricted Reporting when:

(i) DoD law enforcement informs the SARC of the investigation, and

(ii) The victim has not already elected Restricted Reporting.

(2) The timing of filing a Restricted Report is crucial. In order to take advantage of the Restricted Reporting option, the victim must file a Restricted Report by signing a DD Form 2910 before the SARC is informed of an ongoing independent investigation of the sexual assault.

(i) If a SARC is notified of an ongoing independent investigation and the victim has not signed a DD Form 2910 electing Restricted Report, the SARC must inform the victim that the option to file a Restricted Report is no longer available. However, all communications between the victim and the victim advocate will remain privileged, subject to regulatory exceptions, except for the minimum necessary to make the Unrestricted Report.

(ii) If an independent investigation begins after the victim has formally elected Restricted Reporting (by signing the DD Form 2910), the independent investigation has no impact on the victim's Restricted Report, and the victim's communications and SAFE Kit remain confidential, to the extent authorized by law and DoD regulations.

(2) [Reserved]

(d) *Mandatory reporting laws and cases investigated by civilian law enforcement.* Health care may be provided, and SAFE Kits may be performed in a civilian healthcare facility in civilian jurisdictions which may require certain personnel (usually health care personnel) to report the sexual assault to civilian agencies or law enforcement. In some cases, civilian law enforcement may take investigative responsibility for the sexual assault case, or the civilian jurisdiction may inform the military law enforcement or investigative community of a sexual assault that was reported to it. In such instances, it may not be possible for a victim to make a Restricted Report or it may not be possible to maintain the report as a Restricted Report. Consistent with the NDAA for FY 2016, to the extent possible, DoD will honor the Restricted Report; however, sexual assault victims need to be aware that the confidentiality afforded their Restricted Report is not guaranteed due to circumstances surrounding the independent investigation and requirements of individual State laws for civilian healthcare facilities.

(e) *Initiating medical care and treatment upon receipt of report.* Healthcare personnel will initiate the emergency care and treatment of sexual assault victims, notify the SARC or the SAPR VA and make appropriate medical referrals for specialty care, if indicated. Upon receipt of a Restricted Report, only the SARC or the SAPR VA will be notified. There will be NO report to DoD law enforcement, a supervisory official, or the victim's chain of command by the healthcare personnel, unless an exception to Restricted Reporting applies or applicable law requires other officials to be notified. For further information see paragraph (c) of Appendix A to this part.

(f) *Victim's perception of the military justice system.* The DoD seeks increased reporting by victims of sexual assault. The Restricted Reporting option is intended to give victims additional time and increased control over the release and management of their personal information and empowers them to seek relevant information and support to make more informed decisions about participating in the criminal investigation. A victim who receives support, appropriate care and treatment, and is provided an opportunity to make an informed decision about a criminal investigation is more likely to develop increased trust of the system which may increase a victim's desire to cooperate with an investigation and convert the Restricted Report to an Unrestricted Report.

(g) *Resources for victims to report retaliation, reprisal, ostracism, maltreatment, sexual harassment, or to request an expedited/safety transfer or Military Protective Order (MPO)/Civilian Protective Order (CPO).* SARCs and SAPR VAs must inform victims of the resources available to report allegations of retaliation, reprisal, ostracism, maltreatment, sexual harassment, or to request a transfer or MPO. If the allegation is criminal in nature and the victim filed an Unrestricted Report, the crime should be immediately reported to an MCIO, even if the crime is not something normally reported to an MCIO (*e.g.,* victim's personal vehicle was defaced). Victims can seek assistance on how to report allegations by requesting assistance from:

(1) A SARC or SAPR VA or SVC/VLC.

(2) An SVC or VLC, trial counsel and VWAP, or a legal assistance attorney to facilitate reporting with a SARC or SAPR VA.

(3) IG DoD, invoking whistle-blower protections. For further information see paragraph (g) of Appendix A to this part.

(h) *SARC procedures.* The SARC shall:

(1) Serve as the single point of contact to coordinate sexual assault response when a sexual assault is reported. All SARCs shall be authorized to perform victim advocate duties in accordance with Military Service regulations and will be acting in the performance of those duties.

(2) Comply with DoD Sexual Assault Advocate Certification requirements.

(3) Be trained in and understand the confidentiality requirements of Restricted Reporting and MRE 514. Training must include exceptions to Restricted Reporting and MRE 514.

(4) Be authorized to accept reports of sexual assault along with the SAPR VA and healthcare personnel. For further information see paragraph (c) of Appendix A to this part.

(5) Provide a 24 hour, 7 days per week, response capability to victims of sexual assault, to include deployed areas.

(6) In accordance with policy, ensure a safety assessment is performed in every sexual assault case. For further information see paragraph (c) of Appendix A to this part.

(i) SARCs shall respond to every Restricted and Unrestricted Report of sexual assault on a military installation, and the response shall be in person, unless otherwise requested by the victim. For further information see paragraph (c) of Appendix A to this part.

(ii) Based on the locality, the SARC may ask the SAPR VA to respond and speak to the victim.

(A) There will be situations where a sexual assault victim receives medical care and a SAFE outside of a military installation under an MOU or MOA with local private or public sector entities. In these cases, pursuant to the MOU or MOA the SARC or SAPR VA shall be notified, and a SARC or SAPR VA shall respond.

(B) When contacted by the SARC or SAPR VA, a sexual assault victim can elect not to speak to the SARC or SAPR VA, or the sexual assault victim may ask to schedule an appointment at a later time to speak to the SARC or SAPR VA.

(iii) SARCs shall provide a response that recognizes the high prevalence of pre-existing trauma (prior to the present sexual assault incident) and empowers an individual to make informed decisions about all aspects in the reporting process and to access available resources.

(iv) SARCs shall provide a response that is gender-responsive, culturally competent, and recovery-oriented.

(v) SARCs shall offer appropriate referrals to sexual assault victims and facilitate access to referrals. Provide referrals at the request of the victim.

(A) Encourage sexual assault victims to follow-up with the referrals and facilitate these referrals, as appropriate.

(B) In order to competently facilitate referrals, inquire whether the victim is a Reservist or an NG member to ensure that victims are referred to the appropriate geographic location.

(7) Explain to the victim that the services of the SARC and SAPR VA are optional and these services may be declined, in whole or in part, at any time. The victim may decline advocacy services, even if the SARC or SAPR VA holds a position of higher rank or authority than the victim. Explain to victims the option of requesting a different SAPR VA (subject to availability, depending on locality staffing) or continuing without SAPR VA services.

(i) Explain the available reporting options to the victim.

(A) Assist the victim in filling out the DD Form 2910, where the victim elects to make a Restricted or Unrestricted Report. However, the victims, not the SARCs or SAPR VAs, must fill out the DD Form 2910. Explain that sexual assault victims have the right and ability to consult with an SVC/VLC before deciding whether to make a Restricted Report, Unrestricted Report, or no report at all. Additionally, the SARC or SAPR VA shall explain the eligibility requirements for an SVC/VLC, as well as the option to request SVC or VLC services even if the victim does not fall within the eligibility requirements.

(B) Inform the victim that the DD Form 2910 signed by the victim will be uploaded to DSAID and retained for 50 years in Unrestricted Reports. The DD Forms 2910 and 2911 filed in connection with the Restricted Report shall be retained for 50 years, in a manner that protects confidentiality.

(C) The SARC or SAPR VA shall inform the victim of any local or State sexual assault reporting requirements that may limit the possibility of Restricted Reporting. At the same time, the victims shall be briefed about the protections and exceptions to MRE 514.

(ii) Give the victim a hard copy of the DD Form 2910 with the victim's signature. Advise the victim to keep the copy of the DD Form 2910 and the DD Form 2911 in their personal permanent records as these forms may be used by the victim in other matters before other agencies (*e.g.,* Department of Veterans Affairs) or for any other lawful purpose.

(iii) Explain SAFE confidentiality to victims and the confidentiality of the contents of the SAFE Kit. Inform the victim that information concerning the prosecution shall be provided to them. For further information see paragraph (aa) of Appendix A to this part.

(iv) Activate victim advocacy 24 hours a day, 7 days a week, for all incidents of reported sexual assault occurring either on or off the installation involving Service members and other covered persons. For further information see paragraph (c) of Appendix A to this part.

(v) Consult with command legal representatives, healthcare personnel, and MCIOs, (or when feasible, civilian law enforcement), to assess the potential impact of State laws or exceptions governing compliance with the Restricted Reporting option and develop or revise applicable MOUs and MOAs, as appropriate.

(vi) Collaborate with MTFs within their respective areas of responsibility to establish protocols and procedures to direct notification of the SARC and SAPR VA for all incidents of reported sexual assault and facilitate ongoing training of healthcare personnel on the roles and responsibilities of the SARC and SAPR VAs.

(vii) Collaborate with local private or public sector entities that provide medical care to Service members or TRICARE eligible beneficiaries who are sexual assault victims and a SAFE outside of a military installation through an MOU or MOA.

(viii) Establish protocols and procedures with these local private or public sector entities to facilitate direct notification of the SARC for all incidents of reported sexual assault and facilitate training of healthcare personnel of local private or public sector entities on the roles and responsibilities of SARCs and SAPR VAs, for Service members and persons covered by this policy.

(ix) Provide off installation referrals to civilian resources available to sexual assault victims, as needed.

(x) Document and track the services referred to and requested by the victim from the time of the initial report of a sexual assault through the final case disposition or until the victim no longer desires services.

(xi) Maintain in DSAID an account of the services referred to and requested by the victim for all reported sexual assault incidents, from medical treatment through counseling, and from the time of the initial report of a sexual assault through the final case disposition or until the victim no longer desires services. Should the victim return to the SARC or SAPR VA and request SAPR services after indicating that he or she no longer desired services, the case will be reopened and addressed at the CMG meeting.

(xii) A SARC will open a case in DSAID as an ''Open with Limited Information'' case when there is no signed DD 2910 (*e.g.,* an independent investigation or third-party report, or when a civilian victim alleged sexual assault with a Service member subject) to comply with section 563(d) of Public Law 110–417 and to ensure system accountability.

(xiii) Participate in the CMG to review individual cases of Unrestricted Reports of sexual assault.

(xiv) Offer victims the opportunity to participate in surveys asking for victim feedback on the reporting experience. Inform victims regarding what the survey will ask them and uses of the data collected.

(i) *SAPR VA procedures.* (1) The SAPR VA shall:

(i) Comply with DoD Sexual Assault Advocate Certification requirements in D–SAACP.

(ii) Be trained in and understand the confidentiality requirements of Restricted Reporting and MRE 514. Training must include exceptions to Restricted Reporting and MRE 514.

(iii) Facilitate care and provide referrals and non-clinical support to the adult victim of a sexual assault. Provide a response consistent with requirements for the SARC response. For further information see paragraph (c) of Appendix A to this part.

(iv) Support will include providing information on available options and resources so the victim can make informed decisions about his or her case.

(v) Be notified and immediately respond upon receipt of a report of sexual assault.

(vi) Provide coordination and encourage victim service referrals and ongoing non-clinical support to the victim of a reported sexual assault and facilitate care in accordance with the Sexual Assault Response Protocols prescribed SAPR Policy Toolkit located on *www.sapr.mil.* Assist the victim in navigating those processes required to obtain care and services needed. It is neither the SAPR VA's role nor responsibility to be the victim's mental health provider or to act as an investigator.

(vii) Report directly to the SARC while carrying out sexual assault advocacy responsibilities.

(2) [Reserved]

(j) *Healthcare professional procedures.* This paragraph (j) provides guidance on medical management of victims of sexual assault to ensure standardized, timely, accessible, and comprehensive healthcare for victims of sexual assault, to include the ability to elect a SAFE Kit. This policy is applicable to all MHS personnel who provide or coordinate medical care for victims of sexual assault covered by this part.

(1) Require that a SARC be immediately notified when a victim discloses a sexual assault so that the SARC can inform the victim of both reporting options (Restricted and Unrestricted) and all available services (*e.g.,* SVC/VLC, Expedited Transfers, Military Protective Orders, document retention mandates). The victim can then make an informed decision as to which reporting option to elect and which services to request (or none at all). The victim is able to decline services in whole or in part at any time.

(2) There must be selection, training, and certification standards for healthcare providers performing SAFEs in MTFs.

(i) *Selection.* (A) Have specified screening and selection criteria consistent with Public Law 112–81. For further information see paragraphs (h) and (ff) of Appendix A to this part.

(B) In addition to the requirements in Public Law 104–191, licensed DoD providers eligible to take SAFE training must pass a National Agency Check that will determine if they have been convicted of sexual assault, child abuse, domestic violence, violent crime (as defined by the Federal Bureau of Investigation's Uniform Crime Reporting Program) or other felonies.

(C) If the candidate is a non-licensed professional, he or she must meet the same screening standards as those for SARCs in the D–SAACP certification program.

(ii) *Training for healthcare providers performing SAFEs in MTFs.* Healthcare providers who may be called on to provide comprehensive medical treatment to a sexual assault victim, including performing SAFEs, are: Obstetricians, gynecologists, and other licensed practitioners (preferably family physicians, emergency medicine physicians, and pediatricians); advanced practice nurses with specialties in midwifery, women's health, family health, and pediatrics; physician assistants trained in family practice or women's health; and registered nurses. These individuals must receive specialized training aimed at preparing them to proficiently perform the duties of conducting a SAFE.

(A) In addition to the responder training requirements and the healthcare personnel training requirements, healthcare providers performing SAFEs shall be trained and remain proficient in conducting SAFEs.

(B) All providers conducting SAFEs must have documented education, training, and clinical practice in sexual assault examinations. For further information see paragraphs (h) and (ff) of Appendix A to this part.

(iii) *Certification.* (A) Provider must pass all selection and screening criteria.

(B) Provider must submit documentation by trainer that healthcare provider has successfully completed SAFE training and is competent to conduct SAFEs independently. Documentation can be in the form of a certificate or be recorded in an electronic medical training tracking system.

(C) Provider must obtain a letter of recommendation from her or his commander.

(D) Upon successful completion of the selection, training, and certification requirements, the designated medical certifying authority will issue the certification for competency. Certification is good for 3 years from date of issue and must be reassessed and renewed at the end of the 3-year period.

(3) In cases of MTFs that do not have an emergency department that operates 24 hours per day, require that a sexual assault forensic medical examiner be made available to a patient of the facility when a determination is made regarding the patient's need for the services of a sexual assault medical forensic examiner. For further information see paragraphs (h) and (ff) of Appendix A to this part.

(i) The MOU or MOA will require that a SARC be notified and that SAFE Kits be collected. For further information see paragraph (c) of Appendix A to this part.

(ii) When the forensic examination is conducted at a civilian facility through an MOU or a MOA with the DoD, the requirements for the handling of the forensic kit will be explicitly addressed in the MOU or MOA. The MOU or MOA with the civilian facility will address the processes for contacting the SARC and for contacting the appropriate DoD agency responsible for accepting custody of the forensic kit.

(4) Require that MTFs that provide SAFEs for Service members or TRICARE eligible beneficiaries through an MOU or MOA with private or public sector entities verify initially and periodically that those entities meet or exceed standards of the recommendations for conducting forensic exams of adult sexual victims. For further information see paragraphs (h) and (ff) of Appendix A to this part. In addition, verify that as part of the MOU or MOA, a SARC or SAPR VA is notified and responds and meets with the victim in a timely manner.

(5) Require that medical providers providing healthcare to victims of sexual assault in remote areas or while deployed have access to the proper equipment for conducting forensic exams. For further information see paragraphs (h) and (ff) of Appendix A to this part.

(6) Implement procedures to provide the victim information regarding the availability of a SAFE Kit, which the victim has the option of refusing. If performed in the MTF, the healthcare provider shall use a SAFE Kit and the most current edition of the DD Form 2911.

(7) Require that care provided to sexual assault victims shall be gender-responsive, culturally competent, and recovery-oriented.

(8) In the absence of a properly trained DoD healthcare provider, the

victim shall be offered the option to be transported to a non-DoD healthcare provider for the SAFE Kit, if the victim wants a forensic exam. Victims who are not beneficiaries of the Military Healthcare System shall be advised that they can obtain a SAFE Kit through a local civilian healthcare provider at no cost. For further information see paragraphs (h) and (ff) of Appendix A to this part.

(9) Upon completion of the SAFE, the sexual assault victim shall be provided with a hard copy of the completed DD Form 2911. Advise the victim to keep the copy of the DD Form 2911 in his or her personal permanent records as this form may be used by the victim in other matters before other agencies (*e.g.,* Department of Veterans Affairs) or for any other lawful purpose.

(10) Require that healthcare personnel maintain the confidentiality of a Restricted Report to include communications with the victim, the SAFE, and the contents of the SAFE Kit, unless an exception to Restricted Reporting applies. For further information see paragraph (c) of Appendix A to this part.

(11) Require that psychotherapy and counseling records and clinical notes pertaining to sexual assault victims contain only information that is required for diagnosis and treatment. Any record of an account of a sexual assault incident created as part of a psychotherapy exercise will remain the property of the patient making the disclosure and should not be retained within the psychotherapist's record.

(i) *Timely medical care.* To comply with the requirement to provide timely medical care, the Surgeons General of the Military Departments shall provide sexual assault victims with priority treatment as emergency cases, regardless of evidence of physical injury, recognizing that every minute a patient spends waiting to be examined may cause loss of evidence and undue trauma. Priority treatment as emergency cases includes activities relating to access to healthcare, coding, and medical transfer or evacuation, and complete physical assessment, examination, and treatment of injuries, including immediate emergency interventions.

(ii) *Clinically stable.* Require the healthcare provider to consult with the victim, once clinically stable, regarding further healthcare options to the extent eligible, which shall include, but are not limited to:

(A) Testing, prophylactic treatment options, and follow-up care for possible exposure to human immunodeficiency virus and other sexually transmitted diseases or infections (STD/I).

(B) Assessment of the risk of pregnancy, options for emergency contraception, and any follow-up care and referral services to the extent authorized by law.

(C) Assessment of the need for behavioral health services and provisions for a referral, if necessary or requested by the victim.

(k) *Safe kit collection and preservation.* For the purposes of the SAPR Program, forensic evidence collection and document and evidence retention shall be completed in accordance with established policy, taking into account the medical condition, needs, requests, and desires of each sexual assault victim covered by this part. For further information see paragraph (c) of Appendix A to this part.

(1) Medical services offered to eligible victims of sexual assault include the ability to elect a SAFE in addition to the general medical management related to sexual assault response, to include medical services and mental healthcare.

(2) The forensic component includes gathering information in DD Form 2911 from the victim for the medical forensic history, an examination, documentation of biological and physical findings, collection of evidence from the victim, and follow-up as needed to document additional evidence.

(3) The process for collecting and preserving sexual assault evidence for the Restricted Reporting option is the same as the Unrestricted Reporting option, except that the Restricted Reporting option does not trigger the official investigative process, and any evidence collected has to be placed inside the SAFE Kit, which is marked with the RRCN in the location where the victim's name would have otherwise been written. The victim's SAFE and accompanying Kit is treated as a confidential communication under this reporting option. The healthcare provider shall encourage the victim to obtain referrals for additional medical, psychological, chaplain, victim advocacy, or other SAPR services, as needed. The victim shall be informed that the SARC will assist them in accessing SAPR services.

(4) The SARC or SAPR VA shall inform the victim of any local or State sexual assault reporting requirements that may limit the possibility of Restricted Reporting before proceeding with the SAFE.

(5) Upon completion of the SAFE in an Unrestricted Reporting case, the healthcare provider shall package, seal, and label the evidence container(s) with the victim's name and notify the MCIO. The SAFE Kit will be retained for 5 years in accordance with section 586 of Public Law 112–81. When the forensic examination is conducted at a civilian facility through an MOU or a MOA with the DoD, the requirement for the handling of the forensic kit will be explicitly addressed in the MOU or MOA. The MOU or MOA with the civilian facility will address the processes for contacting the SARC and for contacting the appropriate DoD agency responsible for accepting custody of the forensic kit. Personal property retained as evidence collected in association with a sexual assault investigation may be returned to the rightful owner of such property after the conclusion of all legal, adverse action and administrative proceedings related to such incidents in accordance with section 538 of Public Law 113–291.

(6) MOUs and MOAs, with off-base, non-military facilities for the purposes of providing medical care to eligible victims of sexual assault shall include instructions for the notification of a SARC (regardless of whether a Restricted or Unrestricted Report of sexual assault is involved), and procedures for the receipt of evidence and disposition of evidence back to the DoD law enforcement agency or MCIO. For further information see paragraph (c) of Appendix A to this part.

(7) Upon completion of the SAFE in a Restricted Reporting case, the healthcare provider shall package, seal, and label the evidence container(s) with the RRCN and store it in accordance with Service regulations. The SAFE Kit will be retained for 5 years in a location designated by the Military Service concerned. When the forensic examination is conducted at a civilian facility through an MOU or an MOA with the DoD, the requirement for the handling of the forensic kit will be explicitly addressed in the MOU or MOA. The MOU or MOA with the civilian facility will address the processes for contacting the SARC and for contacting the appropriate DoD agency responsible for accepting custody of the forensic kit. The 5-year time frame will start from the date the victim signs the DD Form 2910, but if there is no DD Form 2910, the timeframe will start from the date the SAFE Kit is completed.

(8) Any evidence and the SAFE Kit in Restricted Reporting cases shall be stored for 5 years from the date of the victim's Restricted Report of the sexual assault.

(9) The SARC will contact the victim at the 1-year mark of the report to inquire whether the victim wishes to

change his or her reporting option to Unrestricted.

(i) If the victim does not change to Unrestricted Reporting, the SARC will explain to the victim that the SAFE Kit will be retained for a total of 5 years from the time the victim signed the DD Form 2910 (electing the Restricted Report) and will then be destroyed. The DD Forms 2910 and 2911 will be retained for 50 years in a manner that protects confidentiality. The SARC will emphasize to the victim that his or her privacy will be respected and he or she will not be contacted again by the SARC. The SARC will stress it is the victim's responsibility from that point forward, if the victim wishes to change from a Restricted to an Unrestricted Report, to affirmatively contact a SARC before the 5-year SAFE Kit retention period elapses.

(ii) If the victim needs another copy of either of these forms, he or she can request it at this point, and the SARC shall assist the victim in accessing the requested copies within 7 business days. The SARC will document this request in the DD Form 2910.

(iii) At least 30 days before the expiration of the 5-year SAFE Kit storage period, the DoD law enforcement or MCIO shall notify the installation SARC that the storage period is about to expire and confirm with the SARC that the victim has not made a request to change to Unrestricted Reporting or made a request for any personal effects.

(iv) If there has been no change, then at the expiration of the storage period in compliance with established procedures for the destruction of evidence, the designated activity, generally the DoD law enforcement agency or MCIO, may destroy the evidence maintained under that victim's RRCN.

(v) If, before the expiration of the 5-year SAFE Kit storage period, a victim changes his or her reporting preference to the Unrestricted Reporting option, the SARC shall notify the respective MCIO, which shall then assume custody of the evidence maintained by the RRCN from the DoD law enforcement agency or MCIO, pursuant to established chain of custody procedures. MCIO established procedures for documenting, maintaining, and storing the evidence shall thereafter be followed.

(A) The DoD law enforcement agency, which will receive forensic evidence from the healthcare provider if not already in custody, and label and store such evidence shall be designated.

(B) The designated DoD law enforcement agency must be trained and capable of collecting and preserving evidence in Restricted Reports prior to assuming custody of the evidence using established chain of custody procedures.

(10) Evidence will be stored by the DoD law enforcement agency until the 5-year storage period for Restricted Reporting is reached or a victim changes to Unrestricted Reporting.

§ 103.7 Case management for unrestricted reports of sexual assault.

(a) *General.* CMG oversight for Unrestricted Reports of adult sexual assaults is triggered by open cases in DSAID initiated by a DD Form 2910 or an investigation initiated by an MCIO. In a case where there is an investigation initiated by an MCIO, but no corresponding Unrestricted DD Form 2910:

(1) The SARC would have no information for the CMG members. During the CMG, the MCIO would provide case management information to the CMG, including the SARC.

(2) The SARC would open a case in DSAID indicating the case status as ''Open with Limited Information.'' The SARC will only use information from the MCIO to initiate an ''Open with Limited Information'' case in DSAID. In the event that there was a Restricted Report filed prior to the independent investigation, the SARC will not use any information provided by the victim, since that information is confidential.

(b) *Procedures.* (1) The CMG members shall carefully consider and implement immediate, short-term, and long-term measures to help facilitate and assure the victim's well-being and recovery from the sexual assault. They will closely monitor the victim's progress and recovery and strive to protect the victim's privacy, ensuring only those with an official need to know have the victim's name and related details. Consequently, where possible, each case shall be reviewed independently, bringing in only those personnel associated with the case, as well as the CMG chair and co-chair.

(2) The CMG chair shall:

(i) Confirm that the SARCs and SAPR VAs have what they need to provide an effective SAPR response to victims.

(ii) Require an update of the status of each MPO.

(iii) If the victim has informed the SARC of an existing CPO, the chair shall require the SARC to inform the CMG of the existence of the CPO and its requirements.

(iv) After protective order documentation is presented at the CMG from the SARC or the SAPR VA, the DoD law enforcement agents at the CMG will document the information provided in their investigative case file, to include documentation for Reserve Component personnel in title 10 status.

(v) At every CMG meeting, the CMG Chair will ask the CMG members if the victim, victim's family members, witnesses, bystanders (who intervened), SARCs and SAPR VAs, responders, or other parties to the incident have experienced any incidents of retaliation, reprisal, ostracism, or maltreatment. If any allegations are reported, the CMG Chair will forward the information to the proper authority or authorities (*e.g.,* MCIO, Inspector General, MEO). Discretion may be exercised in disclosing allegations of retaliation, reprisal, ostracism, or maltreatment when such allegations involve parties to the CMG. Retaliation, reprisal, ostracism, or maltreatment allegations involving the victim, SARCs, and SAPR VAs will remain on the CMG agenda for status updates, until the victim's case is closed or until the allegation has been appropriately addressed.

(vi) The CMG chair will confirm that each victim receives a safety assessment as soon as possible. There will be a safety assessment capability. The CMG chair will identify installation personnel who have been trained and are able to perform a safety assessment of each sexual assault victim.

(vii) The CMG chair will, if it has not already been done, immediately stand up a multi-disciplinary High-Risk Response Team if a victim is assessed to be in a high-risk situation. The purpose and the responsibility of the High-Risk Response Team is to continually monitor the victim's safety, by assessing danger and developing a plan to manage the situation.

(viii) The High-Risk Response Team (HRRT) shall be chaired by the victim's immediate commander and, at a minimum, include the alleged offender's immediate commander; the victim's SARC and SAPR VA; the MCIO, the judge advocate, and the VWAP assigned to the case; victim's healthcare provider or mental health and counseling services provider; and the personnel who conducted the safety assessment. The responsibility of the HRRT members to attend the HRRT meetings and actively participate in them will not be delegated.

Appendix A to Part 103—Related Policies

The SAPR Program is supported by the following policies:

(a) DoD Directive 6495.01, ''Sexual Assault Prevention and Response (SAPR) Program,'' Change 3, April 11, 2017 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/649501p.pdf*).

(b) Sections 101(d)(3) and 113, chapter 47,[1] and chapter 80 of title 10, United States Code.

(c) DoD Instruction 6495.02, ''Sexual Assault Prevention and Response (SAPR) Program Procedures,'' May 24, 2017, as amended (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649502p.pdf*).

(d) 32 CFR part 158, ''Operational Contract Support.''

(e) DoD Manual 6400.01, Volume 2, ''Family Advocacy Program (FAP): Child Abuse and Domestic Abuse Incident Reporting System,'' August 11, 2016 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/640001m_vol2.pdf*).

(f) Public Law 114–92, ''National Defense Authorization Act for Fiscal Year 2016,'' November 25, 2015.

(g) DoD Directive 7050.06, ''Military Whistleblower Protection,'' April 17, 2015 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/705006p.pdf*).

(h) U.S. Department of Justice, Office on Violence Against Women, ''A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents,'' current version (available at *https://www.ncjrs.gov/pdffiles1/ovw/241903.pdf*).

(i) 32 CFR part 310, ''DoD Privacy Program.''

(j) DoD Manual 6025.18, ''Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DOD Health Care Programs,'' March 13, 2019 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/602518m.pdf?ver=2019-03-13-123513-717*).

(k) Public Law 113–66, ''The National Defense Authorization Act for Fiscal Year 2014,'' December 2013.

(l) Title 5, United States Code.

(m) Public Law 104–191, ''Health Insurance Portability and Accountability Act of 1996,'' August 21, 1996.

(n) DoD Instruction 5505.18, ''Investigation of Adult Sexual Assault in the Department of Defense,'' March 22, 2017, as amended (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/550518p.pdf?ver=2018-02-13-125046-630*).

(o) Sections 584, 585, and 586 of Public Law 112–81, ''National Defense Authorization Act for Fiscal Year 2012,'' December 31, 2011.

(p) Public Law 113–291, ''Carl Levin and Howard P. 'Buck' McKeon National Defense Authorization Act for Fiscal Year 2015,'' December 29, 2014.

(q) DoD Manual 8910.01, Volume 1, ''DoD Information Collections Manual: Procedures for DoD Internal Information Collections,'' June 30, 2014, as amended (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/891001m_vol1.pdf*).

(r) Public Law 110–417, ''The Duncan Hunter National Defense Authorization Act for Fiscal Year 2009,'' October 14, 2008.

(s) DoD Instruction 5545.02, ''DoD Policy for Congressional Authorization and Appropriations Reporting Requirements,'' December 19, 2008 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/554502p.pdf*).

(t) DoD Directive 5124.02, ''Under Secretary of Defense for Personnel and Readiness (USD(P&R)),'' June 23, 2008 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/512402p.pdf*).

(u) Public Law 112–81, ''National Defense Authorization Act for Fiscal Year 2012,'' December 31, 2011.

(v) Department of Defense 2014–2016 Sexual Assault Prevention Strategy,'' April 30, 2014, *https://www.sapr.mil/index.php/prevention.*

(w) DoD Instruction 6495.03, ''Defense Sexual Assault Advocate Certification Program (D–SAACP),'' September 10, 2015 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649503p.pdf*).

(x) Section 577 of Public Law 108–375, ''Ronald Reagan National Defense Authorization Act for Fiscal Year 2005,'' October 28, 2004.

(y) U.S. Department of Defense, ''Manual for Courts-Martial, United States,'' current edition (available at *https://jsc.defense.gov/Portals/99/Documents/MCM2016.pdf?ver=2016-12-08-181411-957*).

(z) Title 10, United States Code.

(aa) DoD Instruction 1030.2, ''Victim and Witness Assistance Procedures,'' June 4, 2004 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/103002p.pdf*).

(bb) DoD Instruction 5505.19, ''Establishment of Special Victim Investigation and Prosecution (SVIP) Capability within the Military Criminal Investigative Organizations (MCIOs),'' February 3, 2015, as amended (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/550519p.pdf*).

(cc) Directive-type Memorandum 14–003, ''DoD Implementation of Special Victim Capability (SVC) Prosecution and Legal Support,'' February 12, 2014, as amended (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dtm/DTM14003_2014.pdf*).

(dd) Title 32, United States Code.

(ee) Sections 561, 562, and 563 of Public Law 110–417, ''Duncan Hunter National Defense Authorization Act for Fiscal Year 2009,'' October 14, 2008.

(ff) U.S. Department of Justice, Office on Violence Against Women, ''National Training Standards for Sexual Assault Medical Forensic Examiners,'' current version (available at *https://www.ncjrs.gov/pdffiles/ovw/241903*).

(gg) DoD Instruction 6025.13, ''Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS),'' February 17, 2011, as amended (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602513p.pdf*).

(hh) Office of the Chairman of the Joint Chiefs of Staff, ''DoD Dictionary of Military and Associated Terms,'' current edition (available at *https://www.jcs.mil/Portals/36/Documents/Doctrine/pubs/dictionary.pdf*).

(ii) DoD 4165.66–M, ''Base Redevelopment and Realignment Manual,'' March 1, 2006 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/416566m.pdf*).

(jj) Public Law 111–84, National Defense Authorization Act for Fiscal Year 2010.

(kk) 10 U.S.C. Chapter 47, Uniform Code of Military Justice.

Dated: June 18, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–13513 Filed 7–14–20; 8:45 am]

BILLING CODE 5001–06–P

[1] Chapter 47 is also known and referred to in this part as ''The Uniform Code of Military Justice (UCMJ).''

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

Update To Access Standards Drive Time Calculations

AGENCY: Department of Veterans Affairs.

ACTION: Guidance.

SUMMARY: This Department of Veterans Affairs (VA) document provides additional information regarding VA's calculation of average drive times for purposes of eligibility determinations for covered veterans to access community care through the Veterans Community Care Program.

DATES: Effective August 14, 2020.

FOR FURTHER INFORMATION CONTACT: Joseph Duran, Office of Community Care (10D), Veterans Health Administration (VHA), Department of Veterans Affairs, Ptarmigan at Cherry Creek, Denver, CO 80209; *Joseph.Duran2@va.gov;* 303–370–1637 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On June 5, 2019, VA published a final rule at 84 FR 26278 to promulgate 38 CFR 17.4000–17.4040 to implement the Veterans Community Care Program established by section 101 of the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018 (MISSION Act), Public Law 115–182.

Section 17.4040 established access standards for purposes of making eligibility determinations under the Veterans Community Care Program under § 17.4010(a)(4). For primary care, mental health care, and non-institutional extended care services, eligibility is established if VA cannot schedule an appointment for the covered veteran with a VA health care

provider for the required care or service: (i) Within 30 minutes average driving time of the veteran's residence; and (ii) Within 20 days of the date of request unless a later date has been agreed to by the veteran in consultation with the VA health care provider. For specialty care, eligibility is established if VA cannot schedule an appointment for the covered veteran with a VA health care provider for the required care or service: (i) Within 60 minutes average driving time of the veteran's residence; and (ii) Within 28 days of the date of request unless a later date has been agreed to by the veteran in consultation with the VA health care provider. VA noted in § 17.4040(b) that to calculate average driving time from the veteran's residence in paragraph (a) of the section, VA would use geographic information system software.

In the preamble to the final rule, VA explained that it was not detailing in regulation a specific methodology for calculating average drive time because it was more veteran-centric to maintain operational flexibility to refine and improve VA's average drive-time calculations in response to experience, feedback and changing real-world conditions. *See* 84 FR 26278, 26299. This final rule further stated that as VA gained more experience with administering the Veterans Community Care Program and received feedback from veterans regarding their experience with the program, VA anticipated refining the tool to calculate average drive times as well as VA systems to improve our consideration of actual conditions that affect travel to receive care and services and to provide more information to veterans regarding calculation of average drive times. *See* 84 FR 26278, 26301. This notice serves to inform the public that VA is will change the geographic information system software used to the calculate average drive times under § 17.4040.

Description of Changes in Calculating Average Drive Times: As described in the final rule establishing the Veterans Community Care Program (84 FR 26278), VA uses a variety of factors, including distance, route options, and speed limits to calculate the average drive time between the veteran's residence (as noted in VA's enrollment system) and VA facilities that offer the type of care needed by the Veteran. The calculation is similar to the calculations used in popular commercial mapping software used for point-to-point driving directions and estimated travel times. The calculated average is used to determine whether the veteran is eligible for community care based on drive time. The final rule also stated that, in response to comments that requested clarification on how VA will calculate average drive times, that some detailed information regarding average drive time calculations and algorithms is proprietary, and VA was unable to disclose the full method used to make the calculations. *See* 84 FR 26278, 26300.

VA recognized the concerns voiced by veterans and members of the public at the time we launched the Veterans Community Care Program regarding how we calculate average drive time and whether we are making the best estimates of average drive times. This notice about planned refinements is the result of VA's efforts to continue improving how we calculate this important component of eligibility.

VA is refining the average drive-time calculations in the online Decision Support Tool (DST) to improve eligibility determination results and response times based on feedback received from veterans and VA staff regarding their experiences with the Veterans Community Care Program since its implementation on June 6, 2019.

Effective August 14, 2020, VA will use a new geographic information system within DST. Under the new system, VA will determine drive times between two addresses by developing ''service areas'' around all VA facilities, which are bands surrounding the facility that reflect drive times in ranges of 10-minute increments, starting with 0–10 minutes, going up to 81–90 minutes. The applicable drive-time standards depend on the type of care being requested (*i.e.,* the veteran can get needed care within 30 minutes' average drive time for primary care, mental health care and extended care services under § 17.4040(a)(1)(i) or within 60 minutes for specialty care services under § 17.4040(a)(2)(i)). Users of the system will get an estimate of the drive time between the veteran's residence and the VA facility in a 10-minute range under the bands, instead of a single-time estimate as in the current system. Covered veterans whose residence address is within a drive-time service area range that exceeds the drive-time standards for the type of care being sought would be determined to be eligible under § 17.4010(a)(4).

The new system will use historical traffic patterns in all searches. The system will calculate average drive times based on historical traffic patterns on Wednesdays at 10 a.m. at the veteran's local time for all searches. We have selected this time and day of the week to reasonably approximate times that veterans would be traveling for appointments, while working within the capabilities of the system and the available data. Historical traffic data will be updated two to three times per year to reflect changes in local travel patterns.

Veterans will benefit from this change in two ways. First, VA believes the new system will better reflect the actual conditions that affect the time it takes for veterans to travel to receive care and services because of the way that historical traffic data will be used and how average travel times will be calculated. Second, we can now offer more information to veterans and the public regarding how VA will calculate average drive times under this new system. While VA is primarily making this change to improve eligibility determination results and response times, it will also impact eligibility under the access standards for some veterans. VA believes the result will be an overall increase in eligibility.

We note that the average drive time is only one element of covered veterans' eligibility for community care. Since VA established the Veterans Community Care Program on June 6, 2019, covered veterans have also been eligible for community care under other criteria (see 38 CFR 17.4010, Veteran Eligibility). For example, covered veterans who would not be considered eligible for community care based solely on the average drive time element of the designated access standard criterion may still be eligible for community care if the veteran and his or her VA provider agree that it is in the best medical interest of the veteran to receive community care. We remain committed to ensuring that covered veterans are referred to community care where it is in their best medical interest, and veterans with concerns about whether they should be referred to the community are always welcome to discuss their options with their VA providers.

Although we are changing the method of calculating average drive times in our DST tool, which may affect some individuals' eligibility, this notice is not changing VA's designated drive time access standard under § 17.4040. The average drive times that establish eligibility under the designated access standards criterion will remain the same after VA updates the average drive-time calculation tool.

VA continues to believe it is more veteran-centric to maintain the operational flexibility to refine and improve VA's calculations in response to experience, feedback and changing real-world conditions, rather than to detail in regulation a specific

methodology or considerations that could constrain VA's ability to improve the calculation of average drive times in the future. For that reason, we will continue to update the public through documents in the **Federal Register** about any changes to how we calculate average drive times for the Veterans Community Care Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document 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. Brooks D. Tucker, Acting Chief of Staff, Department of Veterans Affairs, approved this document on June 23, 2020 for publication.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2020–14341 Filed 7–14–20; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0633; FRL–10011–25–Region 9]

Air Plan Approval; Arizona; Maricopa County Air Quality Department and Pima County Department of Environmental Quality

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Maricopa County Air Quality Department (MCAQD) and Pima County Department of Environmental Quality (PCDEQ) portions of the Arizona State Implementation Plan (SIP). These revisions concern emissions of particulate matter (PM) from nonmetallic mineral processing, inactive mineral tailings and slag storage. We are approving local rules that regulate these emission sources under the Clean Air Act (CAA or the Act).

DATES: These rules will be effective on August 14, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2019–0633. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4125 or by email at vineyard.christine@*epa.gov.*

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

Table of Contents

I. Proposed Action

On May 1, 2020 (85 FR 25379), the EPA proposed to approve the following rules into the Arizona SIP.

Local agency	Rule No.	Rule title	Adopted/ revised	Submitted
MCAQD	316	Nonmetallic Mineral Processing	11/07/18	11/19/18
PDEQ	Pima County Code Section 17.16.125.	Inactive Mineral Tailings Impoundment and Slag Storage Area within the Ajo PM Planning Area.	[1] 01/22/19	[2] 05/10/19

[1] Pima County Board of Supervisors adopted PCC Section 17.16.125 on January 22, 2019, with an effective date of February 21, 2019.

[2] ADEQ submitted PCC Section 17.16.125 as part of a larger SIP revision submittal titled ''SIP Revision: Ajo PM_{10} Redesignation Request and Maintenance Plan (May 3, 2019)'' (herein referred to as the ''Ajo PM_{10} SIP''). More specifically, appendix C of the Ajo PM_{10} SIP includes PCC Section 17.16.125 and the related adoption materials. ADEQ submitted the Ajo PM_{10} SIP electronically on May 10, 2019, under cover of a transmittal letter dated May 8, 2019. Herein, EPA is taking final action on the PCC Section 17.16.125 portion of the Ajo PM_{10} SIP. The EPA is taking action on the rest of the Ajo PM_{10} Plan in a separate action (85 FR 34381 (June 4, 2020)).

We proposed to approve these rules because we determined that they comply with the relevant CAA requirements. More specifically, with respect to MCAQD Rule 316, we previously determined that the rule implemented Best Available Control Measures for nonmetallic mineral processing within the Phoenix planning area, and we find that the 2018 amendments to the rule relax no control requirements and generally clarify and enhance the effectiveness of the rule. With respect to Pima County Code (PCC) Section 17.16.125, we find that the rule provides a means to ensure the permanence and enforceability of the fugitive dust controls that have already been implemented in the Ajo PM_{10} planning area and that have brought the area into attainment of the Particulate Matter equal to or less than 10 microns in diameter (PM_{10}) National Ambient Air Quality Standards (NAAQS). Our proposed action and related technical support documents (TSDs) contain more information on the rules and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

Pursuant to section 110(k)(3) of the CAA, and for the reasons discussed in detail in our proposed rule and TSDs, and summarized above, the EPA is fully approving MCAQD Rule 316, as submitted on November 19, 2018, and PCC Section 17.16.125, as submitted on May 10, 2019, as revisions to the Arizona SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the

incorporation by reference of the MCAQD and PCDEQ rules described in the amendments to 40 CFR part 52 set forth below. Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[3] The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: June 23, 2020.

John Busterud,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart D—Arizona

■ 2. Section 52.120(c) is amended as follows:

■ a. In Table 4, under the table headings ''Post-July 1988 Rule Codification'' and ''Regulation III—Control of Air Contaminants,'' by revising the entry for ''Rule 316.''

■ b. In Table 7, under the table heading ''Post-1993 Rule Codification,'' by adding the subheadings ''Chapter 17.16. Emission Limiting Standards'' and ''Article III. Emissions from Existing and New Nonpoint Sources'' and an entry for ''17.16.125'' after the entry for ''17.12.480.''

The revision and additions read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

[3] 62 FR 27968 (May 22, 1997).

TABLE 4—EPA-APPROVED MARICOPA COUNTY AIR POLLUTION CONTROL REGULATIONS

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Post-July 1988 Rule Codification				
*	*	*	*	*
Regulation III—Control of Air Contaminants				
*	*	*	*	*
Rule 316	Nonmetallic Mineral Processing.	November 7, 2018	7/15/2020, [INSERT **FEDERAL REGISTER** CITATION].	Submitted on November 19, 2018.
*	*	*	*	*

* * * * *

TABLE 7—EPA-APPROVED PIMA COUNTY AIR POLLUTION CONTROL REGULATIONS

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Post-1993 Rule Codification				
*	*	*	*	*
Chapter 17.16. Emission Limiting Standards				
Article III. Emissions from Existing and New Nonpoint Sources				
17.16.125	Inactive Mineral Tailings Impoundment and Slag Storage Area within the Ajo PM_{10} Planning Area.	February 21, 2019	7/15/2020, [INSERT **FEDERAL REGISTER** CITATION].	Submitted on May 10, 2019.

* * * * *

[FR Doc. 2020–14001 Filed 7–14–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0088; FRL–10011–00-Region 9]

Air Plan Revisions; California; Technical Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to delete various local rules from the California State Implementation Plan (SIP) that were approved in error. These rules include general nuisance provisions, Federal New Source Performance Standards or National Emission Standards for Hazardous Air Pollutant requirements, hearing board procedures, variance provisions, and local fee provisions. The EPA has determined that the continued presence of these rules in the SIP is potentially confusing and thus problematic for affected sources, the State, local agencies, and the EPA. The intended effect is to delete these rules to make the SIP consistent with the Clean Air Act. The EPA is also taking final action to make certain other corrections to address errors made in previous actions taken by the EPA on California SIP revisions are finalized.

DATES: This rule will be effective on August 14, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket No. EPA–R09–OAR–2020–0088. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business information or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Kevin Gong, Rules Office, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3073, *gong.kevin@epa.gov.*

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

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I. Proposed Action

On April 22, 2020 (85 FR 22384), pursuant to section 110(k)(6) of the Clean Air Act (CAA or ''Act''), the EPA proposed to delete various local rules from the California State Implementation Plan (SIP) that were approved in error. These rules include general nuisance provisions, Federal New Source Performance Standards or National Emission Standards for Hazardous Air Pollutant requirements, hearing board procedures, variance provisions, and local fee provisions. The EPA proposed to delete the rules based on the Agency's determination that the rules were approved in error and that the continued presence of these rules in the SIP is potentially confusing and thus problematic for affected sources, the State, local agencies, and the EPA. Table 1 in the proposed rule lists the specific rules that were proposed for deletion.[1]

In our April 22, 2020 proposed rule, the EPA also proposed to make certain other corrections to address errors made in previous actions taken by the EPA on California SIP revisions.[2] One such correction includes the reinstatement in the applicable SIP of the following rules that were previously incorporated by reference but that were erroneously deleted: San Diego County APCD Rule 67.0 ''Architectural Coatings'' (adopted on December 4, 1990 and submitted to the EPA on May 13, 1991), and Tuolumne County APCD Rule 516 ''Upset and Breakdown Conditions'' (excluding paragraph (C) (adopted on September 8, 1981 and submitted to the EPA on October 23, 1981). Other types of corrections include deletion of rules that were previously deleted but for which the deletion was not codified, and other revisions to address errors in amendatory instructions and publishing errors and to clarify the documents that were previously approved.

In our proposed rule, we also proposed to codify the approval of (and incorporate by reference) the following rules that were previously approved but inadvertently not incorporated by reference: San Diego County APCD Rule 20.1 ''Definitions'' (submitted to the EPA on January 28, 1981) and Yolo-Solano Rules 3.4.1 ''Standards for Granting Applications'' and 3.4.2 ''Conditional Approval'' (both submitted to the EPA on February 25, 1980). We are deferring the codification (and incorporation by reference) of San Diego County APCD Rule 20.1 and Yolo-Solano APCD Rules 3.4.1 and 3.4.2 due to the difficulties in preparing the hard copy documents that are necessary for transmittal to the Office of the Federal Register, for the purposes of incorporation by reference, while shelter-in-place orders remain in effect where Region IX offices and employees are located. We note that the versions of San Diego County APCD Rule 20.1 and Yolo-Solano APCD Rules 3.4.1 and 3.4.2 discussed in this paragraph have been superseded by the EPA's approval of further amended rules,[3] and thus, the San Diego rule and Yolo-Solano AQMD rules are no longer part of the current applicable SIP for their respective portions of the California SIP. We had proposed to codify their approvals to maintain an accurate accounting of the versions of the rules that applied for federal enforcement purposes at different times in the past.

An explanation of the relevant CAA requirements and the rationale for each of the proposed deletions and corrections were provided in the proposed rule and will not be restated here.

II. Public Comments and EPA Responses

The public comment period for the EPA's proposed actions closed on May 22, 2020. The EPA did not receive any public comments.

III. EPA Action

Under CAA section 110(k)(6), the EPA is taking final action to delete the rules listed in Table 1 of the April 22, 2020 proposed rule and any earlier versions of these rules from the corresponding air pollution control district portions of the California SIP. The EPA is taking this action based on our determination that the rules were previously approved into the applicable California SIP in error. We are also taking final action to make certain other corrections to fix errors in previous rulemakings on California SIP revisions as described in detail in the April 22, 2020 proposed rule and summarized above.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely corrects errors in previous rulemakings on SIP revisions and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible

[1] See 85 FR 22384, at 22385–22387.

[2] See 85 FR 22384, at 22388–22391.

[3] Even if the EPA's approval of San Diego County APCD Rule 20.1 (''Definitions''), as submitted on January 28, 1981, had been properly codified, it would have been superseded by the EPA's approval of Rule 20.1 (''New Source Review—General Provisions'') at 83 FR 50007 (October 4, 2018). The same is true for Yolo-Solano AQMD's Rules 3.4.1 and 3.4.2. Yolo-Solano AQMD Rule 3.4.1 would have been superseded by the EPA's approval of Rule 3.1 (''General Permit Requirements''), sections 303.2 and 303.3, at 62 FR 36214 (July 7, 1997). Yolo-Solano AQMD Rule 3.4.2 would have been superseded by approval of Rule 3.1 (''General Permit Requirements''), section 402, at 62 FR 36214 (July 7, 1997).

methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (*see* section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: June 23, 2020.

John Busterud,

Regional Administrator, Region IX.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart F—California

■ 2. Section 52.220 is amended by:
■ a. Adding paragraphs (b)(2)(vii), (b)(3)(iii), and (b)(4)(iii);
■ b. Redesignating paragraph (b)(5)(i) as paragraph (c)(6)(xxiv)(D);
■ c. Adding paragraphs (b)(8)(ii), (b)(10)(iii), (b)(11)(iii), (b)(22) through (24), (c)(6)(i)(F), (c)(6)(iv)(D), (c)(6)(vii)(D), (c)(6)(ix)(C), (c)(6)(x)(D), (c)(6)(xii)(D), (c)(6)(xiii)(D), (c)(6)(xiv)(D), and (c)(6)(xviii)(B) and (C);
■ d. Revising paragraph (c)(6)(xxiii)(A);
■ e. Adding reserved paragraph (c)(6)(xxiii)(B) and paragraph (c)(6)(xxiv)(C);
■ f. Removing and reserving paragraphs (c)(21)(vii)(B);
■ g. Adding paragraph (c)(24)(iv)(D);
■ h. Removing and reserving paragraphs (c)(24)(x)(C), (D), and (E);
■ i. Adding paragraphs (c)(25)(i)(G), (c)(25)(iv)(C), (c)(28)(v)(B), and (c)(29)(ii)(C);
■ j. Removing and reserving paragraph (c)(29)(v)(B);
■ k. Adding paragraphs (c)(32)(iii)(H), (c)(44)(iv)(E), and (c)(52)(v)(D);
■ l. Redesignating paragraph (c)(52)(vi)(D) as paragraph (c)(52)(vii)(D);
■ m. Removing and reserving paragraphs (c)(52)(xix)(B) and (c)(54)(v)(C);
■ n. Adding paragraphs (c)(82) introductory text, (c)(83) introductory text, (c)(83)(i) introductory text, and (c)(83)(iii) introductory text;
■ o. Redesignating paragraph (c)(102)(ii)(B) as paragraph (c)(102)(i)(B);
■ p. Adding reserved paragraph (c)(102)(ii)(B);
■ q. Revising paragraph (c)(103)(xvii)(B);
■ r. Adding paragraphs (c)(103)(xvii)(E) and (c)(171)(i)(D)(*7*);
■ s. Revising paragraph (c)(172) introductory text;
■ t. Adding paragraphs (c)(176)(i)(A)(*2*), (c)(183)(i)(E) introductory text, and (c)(184)(i)(D)(*1*) and reserved paragraph (c)(184)(i)(D)(*2*);
■ u. Redesignating paragraph (c)(214)(i)(C)(*3*) as paragraph (c)(423)(i)(E)(*7*);
■ v. Adding paragraph (c)(241)(i)(C)(*4*);
■ w. Redesignating paragraph (c)(307)(i)(C)(*3*) as paragraph (c)(423)(i)(H)(*1*);
■ x. Adding reserved paragraph (c)(423)(i)(H)(*2*); and
■ y. Redesignating paragraph (c)(390)(i)(B)(*1*) as paragraph (c)(389)(i)(B)(*5*).

The additions and revisions read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(b) * * *

(2) * * *

(vii) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement, Section 51.

(3) * * *

(iii) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement, Rule 4:4.

(4) * * *

(iii) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement, Rule 120.

* * * * *

(8) * * *

(ii) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement, Regulation VI.

* * * * *

(10) * * *

(iii) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement, Rule 4.2.

(11) * * *

(iii) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement, Rules 2.5 and 2.6.

* * * * *

(22) Tulare County Air Pollution Control District.

(i) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement, Sections 507, 508 and 515.

(ii) [Reserved]

(23) San Luis Obispo County Air Pollution Control District.

(i) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement, Rule 111.

(ii) [Reserved]

(24) Santa Barbara County Air Pollution Control District.

(i) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement, Rule 17.

(ii) [Reserved]

(c) * * *

(6) * * *

(i) * * *

(F) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rule 51.

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(iv) * * *

(D) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rules 418 and 419.

* * * * *

(vii) * * *

(D) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rules 419 and 420.

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(ix) * * *

(C) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rules 418 and 419.

(x) * * *

(D) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rules 418 and 419.

* * * * *

(xii) * * *

(D) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rules 418 and 419.

(xiii) * * *

(D) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rule 419.

(xiv) * * *

(D) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rule 419.

* * * * *

(xviii) * * *

(B) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rule 45.

(C) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rules 100, 101, and 102.

* * * * *

(xxiii) * * *

(A) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rule 2.17 and 2.19.

* * * * *

(xxiv) * * *

(C) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rule 51.

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(24) * * *

(iv) * * *

(D) Previously approved on May 18, 1977 in paragraph (c)(24)(iv)(A) of this section and now deleted without replacement, Rules 418 and 505.

* * * * *

(25) * * *

(i) * * *

(G) Previously approved on August 22, 1977 in paragraph (c)(25)(i)(A) of this section and now deleted without replacement, Rule 111.

* * * * *

(iv) * * *

(C) Previously approved on August 22, 1977 in paragraph (c)(25)(iv)(A) of this section and now deleted without replacement, Rule 420.

* * * * *

(28) * * *

(v) * * *

(B) Previously approved on August 22, 1977 in paragraph (c)(28)(v)(A) of this section and now deleted without replacement, Rule 205.

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(29) * * *

(ii) * * *

(C) Previously approved on June 2, 1977 in paragraph (c)(29)(ii)(B) of this section and now deleted without replacement, Rules 112 and 113.

* * * * *

(32) * * *

(iii) * * *

(H) Previously approved on June 14, 1978 in paragraph (c)(32)(iii)(C) of this section and now deleted without replacement, Rule 511.

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(44) * * *

(iv) * * *

(E) Previously approved on January 29, 1979 in paragraph (c)(44)(iv)(A) of this section and now deleted without replacement, Rule 5.1.

* * * * *

(52) * * *

(v) * * *

(D) Previously approved on December 9, 1981 in paragraph (c)(52)(v)(B) of this section and now deleted without replacement, Rule 511.

* * * * *

(82) Revised regulations for the following APCD submitted on May 1, 1980, by the Governor's designee.

* * * * *

(83) Revised regulations for the following APCDs submitted on May 13, 1980, by the Governor's designee.

(i) Bay Area Air Quality Management District.

* * * * *

(iii) Fresno County Air Pollution Control District.

* * * * *

(103) * * *

(xvii) * * *

(B) Previously approved on May 27, 1982 in paragraph (c)(103)(xvii)(A) of this section and now deleted without replacement, Rule 516 (paragraph (C)).

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(E) Previously approved on May 27, 1982 in paragraph (c)(103)(xvii)(A) of this section and now deleted without replacement, Rules 703 and 710.

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(171) * * *

(i) * * *

(D) * * *

(*7*) Previously approved on April 12, 1989 in paragraph (c)(171)(i)(D)(*1*) of this section and now deleted without replacement, Rule 4:2.

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(172) Revised regulations for the following APCD's were submitted on March 18, 1987, by the Governor's designee.

* * * * *

(176) * * *

(i) * * *

(A) * * *

(*2*) Previously approved on October 23, 1989 in paragraph (c)(176)(i)(A)(*1*) of this section and now deleted without replacement, Rule 4.2–1.

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(183) * * *

(i) * * *

(E) Santa Barbara County Air Pollution Control District.

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(184) * * *

(i) * * *

(D) * * *

(*1*) Rule 67.0, adopted on December 4, 1990.

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(241) * * *

(i) * * *

(C) * * *

(*4*) Previously approved on July 21, 2000 in paragraph (c)(241)(i)(C)(*2*) of this section and now deleted without replacement, Rule 74.6.3.

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[FR Doc. 2020–13997 Filed 7–14–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC–2019–0063]

RIN 0920–AA72

Control of Communicable Diseases; Importation of Human Remains

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is issuing this Final Rule (FR) to amend two provisions within its Foreign Quarantine regulations to best protect the public health of the United States. The provisions in this Final Rule clarify various safeguards to prevent the importation and spread of communicable diseases affecting human health into the United States from threats posed by human remains.

DATES: This rule is effective August 14, 2020. Direct written comments regarding the Paperwork Reduction Act (PRA) items contained in this document by August 14, 2020.

FOR FURTHER INFORMATION CONTACT: For information regarding this Final Rule: Ashley C. Altenburger, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–H16–4, Atlanta, GA 30329. For information regarding CDC operations related to this Final Rule: ATTN: Kendra Stauffer, D.V.M., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–V–18–2, Atlanta, GA 30329. Either person may also be reached by telephone 404–498–1600 or email *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION:

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I. Public Participation

On November 25, 2019, HHS/CDC published a notice of proposed rulemaking (NPRM) (84 FR 64808) to amend 42 CFR part 71 (Foreign Quarantine). The public was invited to comment on these amendments. In the NPRM, HHS/CDC specifically requested public comment on the following:

- Proposed Definitions for ''death certificate,'' ''human remains,'' ''importer,'' and ''leak-proof container.''
- Whether other valid documents should be accepted in lieu of a death certificate.
- The applicability of 42 CFR 71.63 to 42 CFR 71.55.
- The costs to importers to support inspections and respond to CDC questions.
- Repackaging costs or decomposition costs.

The public comment period for the proposed rule ended on January 24, 2020, and HHS/CDC received three comments from the public. A summary of those comments and responses to those comments are found at Section IV, below.

II. Background

A. Legal Authority

The primary legal authorities supporting this rulemaking are sections 361 and 362 of the Public Health Service Act (42 U.S.C. 264 and 265). Section 361 authorizes the Secretary [1] of HHS to make and enforce such regulations as in the Secretary's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the states or possessions of the United States or from one state or possession into any other state or possession. A detailed explanation of these legal authorities was provided in the NPRM published at 84 FR 64809.

[1] 42 U.S.C. 264 and 265 by their terms grant authority to the U.S. Surgeon General. The Reorganization Plan No. 3 of 1966 abolished the Office of the Surgeon General and transferred the Surgeon General's functions to the Secretary of Health, Education, and Welfare (now Secretary of HHS). 31 FR 8855, 80 Stat. 1610 (Jun. 25, 1966). The Secretary of Health, Education, and Welfare was re-designated the Secretary of Health and Human Services by section 509(b) of Public Law No. 96–88, 93 Stat. 695 (codified at 20 U.S.C. 3508(b)). Although the Office of the Surgeon General was re-established in 1987, the Secretary of HHS has retained the authority for carrying out the functions of the Surgeon General under 42 U.S.C. 264 and 265.

B. Regulatory History

On November 25, 2019, HHS/CDC published a Notice of Proposed Rulemaking to update 42 CFR 71.50 and 42 CFR 71.55 within its Foreign Quarantine regulations to address the risk to public health from the importation of human remains into the United States. The provisions contained within the proposal were designed to enhance HHS/CDC's ability to prevent the importation and spread of communicable diseases into the United States and interstate by clarifying for the public HHS/CDC's capabilities and current practices, while also making them more transparent.

III. Summary of the Final Rule

To best reflect current practice, HHS/CDC has renamed 42 CFR 71.55 ''Importation of Human Remains'' to clarify that our authority extends to portions of the human body, and not only to ''dead bodies'' as a whole, as well as to highlight the difference in documentation needed between human remains imported for final resting (under § 71.55) and human body parts primarily imported for other reasons, which may fall under § 71.54 ''Import regulations for infectious biological agents, infectious substances, and vectors.'' Also for added clarity, HHS/CDC has included four new definitions under 42 CFR 71.50 *Scope and definitions,* which is applicable to importations under part 71 subpart F: ''death certificate,'' ''human remains,'' ''importer,'' and ''leak-proof container.''

Updated 42 CFR 71.55(a), now states that all human remains intended for import into the United States and those transiting through the United States *en route* to a foreign destination must be contained in a leak-proof container that is packaged and shipped in accordance with all applicable legal requirements. This requirement will ensure that individuals handling the packages of human remains are not exposed to body fluids that may contain an infectious biological agent or embalming material, regardless of whether the remains are intended for importation or are in transit through the United States.

Section 71.55(b) informs the public that imports of human remains known to contain or reasonably suspected of containing an infectious biological agent must abide by 42 CFR 71.54 to ensure that all measures are taken to protect U.S. public health. This includes remains known to contain or reasonably suspected of containing an infectious biological agent that have not or cannot be rendered noninfectious.

Under § 71.55(c)(1)(i), to ensure that human remains imported for final resting enter only for the intended purpose, we have included a requirement that such remains be consigned ''directly'' to a licensed mortuary, cemetery, or crematory. Section 71.55(c)(1)(ii), requires that these remains (unless embalmed) must also be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent. Such documentation ensures that the human remains do not pose a threat to public health because the decedent succumbed to a communicable disease, including a quarantinable communicable disease.

Under § 71.55(c)(2)(i), if human remains are imported for medical examination or autopsy, the remains must be consigned directly to an entity authorized to perform such functions under the laws of the applicable jurisdiction prior to subsequent burial, entombment, or cremation. By ''authorized,'' HHS/CDC includes government entities that typically perform medical examinations or autopsies such as state or local coroners' offices, as well as private entities operating in compliance with the laws of the relevant jurisdiction. Upon completion of the medical examination or autopsy, the human remains must be immediately delivered to a licensed mortuary, cemetery, or crematory that will be responsible for final resting. Section 71.55(c)(2)(ii), requires that these remains (unless embalmed) be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent. Such documentation ensures that the human remains being imported do not pose a threat to public health because the decedent succumbed to a communicable disease, including a quarantinable communicable disease.

Section 71.55(c)(3) requires that, unless embalmed, all ''human remains'' (as that term is defined) imported into the United States for purposes other than final resting or autopsy be accompanied by an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent. This language addresses the other uses for human remains such as medical training or anatomical display.

Finally, under § 71.55(d), the CDC Director may suspend the entry or importation of human remains under 42 CFR 71.63 if the Director determines that such an action is necessary to protect the public health. Such an action may occur when (i) the import is coming from a foreign country designated by the CDC Director as a place where a communicable disease exists that could threaten U.S. public health and (ii) the import increases the risk of introducing or spreading the communicable disease into the United States. In the past, this provision has only been invoked to temporarily suspend wildlife reservoirs of zoonotic disease and HHS/CDC does not anticipate that this provision will be invoked frequently absent a public health emergency where such measures would be needed to protect U.S. public health.

As in the proposal, HHS/CDC notes that certain federal partners, such as the Department of Defense (DOD) and the Department of State (DOS), may require that human remains of military or civilian personnel continue on to a place of final resting outside of the United States after the remains are transported into the United States. Such a transport will not be deemed an ''import'' under this Final Rule and therefore will not be subject to the requirement that remains be consigned ''directly'' to a licensed mortuary, cemetery, or crematory, because the remains are ''transiting'' through the United States *en route* to final destination. We note also that, under this Final Rule, HHS/CDC will not prevent human remains from transiting through a U.S. port of entry *en route* to another country, provided that the remains are properly packaged in a leak-proof container and in compliance with applicable transportation requirements.

Upon consideration of the public comments received, HHS/CDC did not make any changes to the language proposed to amend part 71 as set forth in the November 2019 NPRM (84 FR 64808). Therefore, this regulation is finalized as proposed.

IV. Overview of Public Comments to the 2019 NPRM

On November 25, 2019, HHS/CDC published a Notice of Proposed Rulemaking proposing to amend the current foreign quarantine regulations for the control of communicable diseases. The NPRM included a 60-day public comment period and during this time, HHS/CDC received three comments from the public.

All comments received were in support of this regulation. All three of the commenters expressed that this regulation is important for safeguarding public health. In addition, one commenter expressed that the updated regulation ''represent[s] an appropriate response to complaints concerning public health'' and ''the updated definition and unambiguous re-codification of these provisions are simple enough for a (sic) someone lacking education in medicine to understand and can be adhered to by almost anyone.'' Furthermore, another commenter expressed that ''. . . these new provisions would be a good idea to amend, as they make the process of bringing remains to the United States safer [. . .] these additional safety nets are needed, especially when regarding public health.''

HHS/CDC thanks the commenters for their input on the proposed rule.

V. Alternatives Considered

As discussed in more detail above and analyzed in VI(A), HHS/CDC amends two provisions within its foreign quarantine regulations (specifically, 42 CFR 71.50 and 71.55) to provide additional clarity and safeguards to address the risk to public health from the importation of human remains into the United States.

In addition to quantitatively analyzing the economic impact of providing additional clarity and safeguards to address the public health risk from importation of human remains relative to the status quo baseline, HHS/CDC also considered alternatives to this Final Rule. HHS/CDC considered alternatives that were both more and less burdensome than the amendments to 42 CFR 71.50 and 71.55 described in this Final Rule.

First, HHS/CDC considered whether a leak-proof container was necessary for importing human remains. If HHS/CDC did not specify leak-proof containers for importation, such an alternative would be a potentially less burdensome requirement than transport of human remains in leak-proof containers. This alternative may potentially reduce the burden of airlines and importers. However, the reduced burden is hard to quantify because it is unclear whether importers or airlines would change their current practices if the less burdensome alternative was chosen. HHS/CDC does not believe this regulatory alternative would significantly change the current status quo baseline.

First, the reduced burden to airlines of this alternative would probably be

minor. The current requirements of the four largest U.S. carriers to ship human remains are already consistent with the HHS/CDC's leak-proof container requirement. If HHS/CDC did not specify that human remains be imported in leak-proof containers, airlines may choose to maintain their existing requirements for transporting human remains internationally in leak-proof containers to avoid exposures to their employees. The usage of leak-proof containers may also be regulated under the U.S. Department of Labor's Occupational Safety and Health Administration's requirements (refer to 29 CFR 1910.1030) after entry through ports of entry.

In addition, importers (other than colleges, hospitals, or laboratories) of human remains for purposes other than burial, entombment, or cremation may already be subject to U.S. Department of Transportation (DOT) packaging requirements delineated in 49 CFR 173.199. These requirements are more burdensome than HHS/CDC's leak-proof container requirement.

Another alternative would be to require a more burdensome requirement, such as a hermetically sealed casket, to import all un-embalmed human remains. This alternative would increase importers' burdens compared to the Final Rule. The increased burden, however, is hard to quantify because of limited data. The cost of this alternative would be much more expensive than the cost associated with the status quo guidance and HHS/CDC does not believe the marginal improvement to public health would justify the substantially increased cost of requiring hermetically sealed caskets to import all un-embalmed human remains. For the purposes of this Final Rule, HHS/CDC will apply an established definition of embalming as the (1) reduction of microorganisms within the dead human body; (2) retarding of organic decomposition, and (3) restoring the deceased to a life-like appearance.[2]

From a public health perspective, embalming of human remains is considered a mechanism to render the remains noninfectious so they no longer pose a risk of exposure to communicable diseases. For some diseases, such as Ebola virus disease, embalming may pose a public health risk to personnel performing the embalming process because of the very high risk of exposure to blood and other body fluids; for these diseases, embalming is not recommended.

HHS/CDC documentation requirements are consistent with existing international agreements and instruments governing the international transportation of human remains as noted in the DOS Foreign Affairs Manual, 7 FAM 252(b).[3] The documentation requirements listed in 42 CFR 71.55(c) only apply to human remains that are not embalmed. Since the majority of human remains imported for burial, entombment, or cremation are embalmed, most importations would not be affected by this codification of current practice.

A less burdensome alternative would be to also eliminate the documentation requirements for un-embalmed human remains. However, as noted in 7 FAM 258, DOS states that the consular mortuary certificate is designed to facilitate U.S. Customs Clearance. In addition, DOS requests a certificate of death, an affidavit by the local funeral director, and a transit permit as required by local laws to support exporting human remains. It should be noted that the documentation requested by DOS to support the transportation of cremated human remains (which are exempt from HHS/CDC requirements) are similar to the requested documentation for non-cremated human remains.[4] In general, HHS/CDC would expect that death certificates or the Affidavit of Foreign Funeral Director and Transit Permit would be created in the event of an overseas death and would be available for most human remains imported for burial, entombment, or cremation. However, it may be necessary to provide either a (translated) death certificate or to translate the Affidavit of Foreign Funeral Director or Transit Permit. Thus, the primary cost may be for translation services for these documents if human remains are imported from a non-English-speaking country. However, since the importation of most human remains are already facilitated by DOS consular offices, translated documentation may already be provided to U.S. consular offices in most cases. Without the documentation required in this Final Rule, it would not be possible for HHS/CDC to confirm that individuals did not die from a quarantinable communicable disease or otherwise pose a public health risk to individuals exposed to their un-embalmed remains. In the past, HHS/CDC has not routinely had issues obtaining these documents for imported, un-embalmed human remains for burial, entombment, or cremation, and did not receive any public comments on the cost or burden of producing such documentation. HHS/CDC believes that the costs associated with increased risk of exposure to un-embalmed human remains infected with communicable diseases justify the expense for the documentation requirements in new 42 CFR 71.55(c), once finalized, for un-embalmed human remains.

A more burdensome documentation requirement would be to require that all importations of human remains (*i.e.,* embalmed remains as well as un-embalmed remains) comply with this documentation requirement. However, HHS/CDC does not believe that the public health risks posed by embalmed human remains (*e.g.,* exposure to embalming fluids) shipped in leak-proof containers necessitate additional documentation requirements for public health purposes.

HHS/CDC also considered an alternative in which different requirements would apply to different countries. However, since most human remains that are imported to the United States were U.S. citizens, permanent residents, or their relatives, HHS/CDC does not generally believe the risk of exposure to communicable diseases is likely to vary depending based on the country from which human remains are imported. HHS/CDC does address the potential need to apply different requirements to different countries in 42 CFR 71.55(d). The CDC Director may suspend the entry or importation of human remains under 42 CFR 71.63 if the Director determines that such an action is necessary to protect the public health. Such an action may occur when (i) the import is coming from a foreign country designated by the CDC Director as a place where a communicable disease exists that could threaten U.S. public health and (ii) the import increases the risk of introducing or spreading the communicable disease into the United States. In the past, this provision has only been invoked to temporarily suspend wildlife reservoirs of zoonotic disease such as suspension of six genera of African rodents to prevent further importation of monkeypox virus during the 2003 monkeypox outbreak. The order was later replaced by an interim Final Rule on November 3, 2003 (42 CFR 71.56 and

[2] The American Board of Funeral Services Education, course content, 2001, and (3) Mayer, RG. Embalming, History, Theory, and Practice, 5th edition. 2012: McGraw-Hill Medical; ISBN 978–0–07–174139–2.

[3] The international agreements and instruments listed in 7 FAM 252(b) are (1) Council of Europe, Agreement on The Transfer Of Corpses, Signed at Strasbourg, October 26th, 1973; (2) Pan American World Health Organization, XVII Pan American Sanitary Conference, XVIII Regional Committee Meeting, Resolution XXIX, adopted in Washington, October 7th, 1966, International Transportation Of Human Remains; and (3) International Arrangements Concerning the Conveyance of Corpses, Signed at Berlin, February 10, 1937.

[4] Refer to 7 FAM 256.

42 CFR 1240.63). HHS/CDC does not anticipate that this provision will be invoked frequently absent a public health emergency where such measures would be needed to protect U.S. public health.

VI. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

Executive Orders 12866 ''Regulatory Planning and Review,'' and 13563 ''Improving Regulation and Regulatory Review,'' direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Statement of Need

As discussed in more detail above, HHS/CDC amends two provisions within its foreign quarantine regulations (specifically, 42 CFR 71.50 and 71.55) to provide additional clarity and safeguards to address the risk to public health from the importation of human remains into the United States. In recent years, HHS/CDC has received an increased number of notifications regarding the importation of body parts that are improperly packaged (*e.g.,* contained in garbage bags or coolers susceptible of leaking fluid) or that lack proper documentation (*e.g.,* importers stating only that the remains are to be used for ''training.'').[5] [6] In some cases, importers have misrepresented the contents of their shipped packages containing human remains, and the shipped containers with human remains were subsequently found to be leaking.

HHS/CDC has two regulatory provisions that control the safe importation of human remains into the United States:

- Under § 71.54, CDC requires an import permit for the importation of a whole body or body part that is known to contain or reasonably suspected of containing an infectious biological agent.
- Under current § 71.55, CDC requires that imported human remains be cremated, or properly embalmed and placed in a hermetically sealed casket, or accompanied by a permit issued by the CDC Director if the cause of death was a quarantinable communicable disease.

Because both §§ 71.54 and 71.55 are applicable to imported human remains, U.S. Customs and Border Protection agents often hold bodies and body parts for several days at the port of entry until a determination is made as to which regulatory provision should apply. While CDC has published guidance on its website, it believes that further rulemaking is needed to address these concerns. Therefore, HHS/CDC is formally amending its regulations to codify current policy, to clarify roles and responsibilities, and to better inform importers what requirements may apply, including when a permit may be needed. These changes are not intended to affect the operations of other federal partners who have a role in either the importation of human remains or the regulation of such imports.

The regulatory changes described in the preamble and reported below are a codification of current requirements authorized under existing 42 CFR 71.32(b), 71.54, 71.55, and 71.63, and described in guidance. Since this Final Rule does not change the regulatory baseline, HHS/CDC expects minimal economic impacts on importers of human remains, Department of Homeland Security/Customs and Border Protection/Transportation Security Administration (DHS/CBP, DHS/TSA,), HHS/CDC, Department of State (DOS), airline or other industries that facilitate the importation of human remains, or state and local public health departments (Ph.D.s).

HHS/CDC regulations are necessary to correct the market failure in which human remains are improperly packaged (*e.g.* contained in garbage bags or coolers susceptible of leaking fluid) or that lack proper documentation that could pose additional risk to individuals in the event of an accidental exposure. These changes should reduce risks of exposure for other non-importer stakeholders (*e.g.,* carrier or vessel staff, other travelers, TSA or CBP staff who inspect cargo) to communicable diseases. The container requirement limits exposures to leaking fluids. The documentation requirements ensure that human remains that pose a public health risk are accompanied with the proper permit documentation under existing 42 CFR 71.54 or, under 42 CFR 71.55(c)(1)(i) are consigned ''directly'' to a licensed mortuary, cemetery, or crematory. If human remains are consigned directly to a licensed mortuary, cemetery, or crematory, the human remains will be handled by professionals with experience handling human remains. Otherwise, the documentation and container requirements would limit others' exposures to human remains or may provide additional information (via the documentation requirements) on potential public health risks in the event of an exposure.

The requirements specified under 42 CFR 71.55(a) conform with existing CDC guidance that human remains should be transported in a leak-proof container that is packaged and shipped in accordance with all applicable legal requirements. For human remains for which the cause of death was a quarantinable communicable disease, HHS/CDC requirements will change from the more burdensome hermetically sealed casket to the less burdensome leak-proof container. These requirements are also consistent with requirements imposed by the four largest U.S. carriers in 2019 for transport of human remains (*i.e.,* Delta, American, United, and Southwest Airlines). In practice, HHS/CDC is unaware of any imported human remains of individuals who died of a quarantinable disease in the previous 15 years. HHS/CDC eliminates specific requirements under current § 71.55 that human remains of a person who died of a quarantinable communicable disease be ''embalmed'' and placed into a ''hermetically sealed casket'' because this no longer reflects current best practices and would unnecessarily increase the burden on importers.

The requirements under 42 CFR 71.55(b) simply refer to existing permit requirements described in 42 CFR 71.54 for all imported human remains known to contain or reasonably suspected of containing an infectious biological agent. There is no change to 42 CFR 71.54, simply clarification in 42 CFR 71.55(b) of when 42 CFR 71.54 should apply to transport of human remains. The requirements under 42 CFR 71.55(c) clarify the documentation requirements for un-embalmed human remains imports that do not need permits according to existing 42 CFR 71.54. These documentation requirements are consistent with existing practices in the Department of State's Foreign Affairs Manual and consistent with other agencies' requirements for transporting human remains to facilitate U.S. Customs Clearance.

DOS works with U.S. residents to process the required documentation for importing human remains into the United States for burial, entombment, or cremation. Their requirements are

[5] *https://www.washingtonpost.com/news/morning-mix/wp/2016/03/26/the-husband-and-wife-duo-who-allegedly-dismembered-diseased-bodies-and-sold-them-for-profit/.*

[6] *https://www.reuters.com/investigates/special-report/usa-bodies-brokers/.*

reported in the current version of the Foreign Affairs Manual (FAM). In 7 FAM 252(a)(3), DOS notes that CDC's authority is not limited to quarantinable communicable diseases but extends to the importation of remains of persons who died of other communicable diseases. Specifically, 7 FAM 252(a)(3) states that ''In general, U.S. public health requirements will be satisfied if the remains are shipped in a leak-proof container and accompanied by the death certificate or the consular mortuary certificate, which must state that the deceased did not die from a quarantinable communicable disease. A leak-proof container is one that is puncture-resistant and sealed in a manner to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping. While additional restrictions are not generally employed, CDC reserves the right to do so on a case-by-case basis when necessary to prevent the spread of disease.''

This description is consistent with the codification of requirements of human remains for the purposes of burial, entombment, or cremation under the new 42 CFR 71.55, once effective, as summarized above. Because this is a codification of current practice, the economic impact on importers of human remains and DOS are expected to be minimal. To estimate the cost to DOS to update the FAM to include references to 42 CFR 71.55, the cost was estimated by assuming that 1 GS–14, step 5 employee and one GS–15, step 5 employee each spend 40 hours (*i.e.,* 80 hours in total) for any updates to cite the language in 42 CFR 71.55. The hourly wage rates for two employees based in Washington-Baltimore-Arlington, DC–MD–VA–WV–PA are $62.23 (GS–14) and $73.20 (GS–15).[7] To account for the non-wage benefits, we multiplied the wage cost by two to result in a total cost estimate of $10,834. The costs for CBP and CDC are expected to be similar (Table 1), because this change is a codification of current practice. Thus, the expected one-time costs associated with codification for all three agencies can be estimated at $31,906.

TABLE 1—SUMMARY OF THE ONE-TIME COSTS IN 2018 USD TO UPDATE OFFICIAL DOCUMENTS FOR DEPARTMENT OF STATE (DOS), CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), AND CUSTOMS AND BORDER PROTECTION (CBP) COSTS FROM THE CODIFICATION IN 42 CFR 71.55 OF THE REQUIREMENTS AUTHORIZED UNDER EXISTING 42 CFR 71.32(b), 71.54, AND 71.63

Agency	Cost components	Hourly wage rate [8]	Multiplier for non-wage benefits and overhead	Total
DOS	80 hours split between GS–14, step 5 and GS–15, step 5 levels	$67.72	2	$10,834
CDC	80 hours split between GS–14, step 5 and GS–15, step 5 levels	63.99	2	10,238
CBP	80 hours split between GS–14, step 5 and GS–15, step 5 levels	67.72	2	10,834
Total				31,906

Individuals importing human remains for purposes other than burial, entombment, or cremation, may be less familiar with CDC requirements authorized under existing 42 CFR 71.32(b) and 71.54. As a result, importers of human remains for other purposes may not be aware of the requirement that human remains must arrive in an appropriate, leak-proof shipping container as specified under new 42 CFR 71.55(a), once effective. In addition, they may not be aware that, unless human remains are embalmed and therefore rendered noninfectious, they must be accompanied by a death certificate listing cause of death or that if the death certificate is incomplete or if cause of death is not listed, the human remains must be accompanied by an importer certification statement either confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent as specified under 42 CFR 71.55(c). In addition, importers would need to apply for a permit under existing 42 CFR 71.54 if they are unable to demonstrate that human remains are not reasonably suspected of containing an infectious biological agent. Upon publishing of this Final Rule, CDC will update its website to ensure that importers have access to the most up-to-date information regarding packaging and documentation requirements for human remains.

The codification of existing requirements should not result in an additional regulatory burden and should help reduce the costs by reducing confusion regarding the requirements for importing human remains for purposes other than burial, entombment or cremation. However, as an upper bound cost estimate, we assumed that one additional importer would apply for a permit to import human remains every other year after the Final Rule goes into effect. When importers first apply for a permit, the greatest expense is associated with the need for DSAT to perform an inspection of the importers' facilities and to document their findings. This process also requires time for importers to support the inspection and respond to questions from DSAT subject matter experts. HHS/CDC estimated the amount of time per inspection to include about 20 hours of staff time split between the GS–12, GS–13, and GS–14 pay levels. To estimate costs, HHS/CDC assumed the staff would be compensated at step 5 as summarized in Table 2. In addition to hourly wages, non-wage benefits and overhead costs were estimated by multiplying the wage cost by two. The average round trip airfare for flights from Atlanta was estimated at $367 using data from the Bureau of Transportation Statistics.[9] The average Federal per diem for lodging, meals, and incidental expenses was estimated at $158 per day for one day.[10] Assuming that inspections occur on average (0.5

[7] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

[8] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

[9] Bureau of Transportation Statistics. Average Domestic Airfares (Atlanta, 2018 Q4). *https://transtats.bts.gov/AIRFARES/.* Accessed on June 19, 2019.

[10] FederalPay.org 2018 Federal Per Diem Rates. (Average of 50 states). *https://www.federalpay.org/perdiem/2018.* Accessed on June 19, 2019.

times per year, the annual cost would be estimated at $1,518 per year.

In addition to CDC costs, importers would have to spend time to support the inspection and respond to CDC questions. HHS/CDC did not receive public comments on the costs to importers to support such inspections. HHS/CDC assumed the amount of time required would be equivalent to CDC staff time (*i.e.,* about 20 hours) and that the individual working on the inspection would be compensated at a rate equivalent to the national average wage rate reported for individuals working as Sales Representatives, Wholesale and Manufacturing, Technical and Scientific Products as reported in the Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates (Occupation code = 41–4011).[11] Their 2018 reported hourly wage rate was $44.15. Assuming 0.5 inspections per year and a multiplier of 2 to cover non-wage benefits and overhead, the annual cost for importers was estimated at $883 per year. In total, the annual cost for increased inspections for CDC ($1,518) and importers ($883) was estimated at $2,401. This should represent an upper bound estimate as HHS/CDC does not anticipate a large increase in inspections as a result of this Final Rule.

TABLE 2—ESTIMATED ANNUAL CDC COST IN 2018 USD FOR INSPECTIONS OF THE FACILITIES FOR AN IMPORTER OF HUMAN REMAINS FOR PURPOSES OTHER THAN FINAL RESTING

Type of CDC staff	Number of staff	Number of inspections per year	Number of hours spent per inspection	Average hourly wage rate [12]	Overhead multiplier	Annual cost
GS–12 (step 5)	0.33	0.5	20	$41.85	2	$276
GS–13 (step 5)	0.33	0.5	20	49.76	2	328
GS–14 (step 5)	0.33	0.5	20	58.80	2	388
Total						993
Travel cost	Airfare [13]	367	Hotel, food, lodging [14]		158	525
Total (personnel + travel)						1,518

The total projected costs over a 10-year time horizon for each government agency and for importers can be estimated using a 3% discount rate. Table 3 summarizes the present value and annualized value of costs over the full 10-year period. In total, the estimated cost is $46,977 over 10 years or an annualized value of $5,507 per year.

TABLE 3—PRESENT VALUE AND ANNUALIZED VALUE OF COSTS IN 2018 USD OVER 10 YEARS USING A 3% DISCOUNT RATE FOR GOVERNMENT AGENCIES AND FOR IMPORTERS OF HUMAN REMAINS FOR PURPOSES OTHER THAN FINAL RESTING

	Net present cost over 10-year horizon	Annualized cost over 10-year horizon
CDC	$18,408	$2,158
CBP	10,518	1,233
DoS	10,518	1,233
Importers of human remains for other purposes	7,532	883
Total	46,977	5,507

In the past, imported human remains for reasons other than burial, entombment or cremation have arrived in inappropriate (*i.e.,* not leak-proof) containers or without sufficient documentation to determine whether such remains may contain or be reasonably suspected of containing an infectious biological agent. This has led to confusion at the port of entry and detention of the human remains pending an investigation. CDC reviewed available importation records and identified six human remains shipments that required repackaging over the 5-year period from 2014 to 2018. Of the six shipments, four occurred between November 2017 and the end of 2018. These investigations required significant effort to resolve. CDC involvement usually includes scientific, legal, policy, and leadership staff from CDC/DGMQ and CDC/DSAT. In each of these cases, CDC determined that a permit issued according to existing 42 CFR 71.54 would be required when human remains are reasonably suspected of containing an infectious biological agent if they are without adequate shipping containers or proper documentation, unless they are cremated, embalmed, or otherwise rendered noninfectious per the definition of ''human remains.''

Although the amount of time per investigation event varies, on average, each importation investigation was

[11] Bureau of Labor Statistics, May 2018 National Occupational Employment and Wage Estimates (Occupation code = 41–4011). *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on June 19, 2019.

[12] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Atlanta-Athens-Clarke county-Sandy Springs, GA–AL Accessed on June 19, 2019.

[13] Bureau of Transportation Statistics. Average Domestic Airfares (Atlanta, 2018 Q4). *https://transtats.bts.gov/AIRFARES/.* Accessed on June 19, 2019.

[14] FederalPay.org 2018 Federal Per Diem Rates. (Average of 50 states). *https://www.federalpay.org/perdiem/2018.* Accessed on June 19, 2019.

estimated to require approximately 600 hours of CDC staff time split between the GS–13, GS–14, and GS–15 levels. The time spent included conference calls with the importer and CBP, legal review, permit issuance under 42 CFR 71.54, if applicable, among other activities (Table 4). The 2018 reported hourly wage rates for GS–13, GS–14, and GS–15 employees at step 5 are $49.76, $58.80, and $69.17 per hour respectively in the Atlanta, GA area.[15] If this amount of time is split evenly across each level, the estimated cost per investigation would be $35,546. This amount can then be multiplied by 2 to account for non-wage benefits and overhead to estimate a total cost of $71,092 per investigation.

In addition to CDC costs, CBP also incurs costs to deal with each investigation including time spent communicating with CDC. The amount of time spent by CBP is also significant and conservatively estimated at 50% of the time spent by CDC staff. The estimated hourly wage rate for CBP officers was estimated by assuming that the workload would be split evenly across employees at the GS–5, GS–9, GS–11, and GS–12 levels with support from GS–15 managers providing additional coordination with CDC senior staff. Thus, compensation was split evenly across grades and each grade was assumed to be compensated at the step 5 level using the Washington-Baltimore-Arlington hourly pay scale (on average, $41.02 per hour).[16] This would result in a wage cost of $12,306. After multiplying wages by 2 to account for non-wage benefits and overtime, the estimated CBP cost would be $24,614. Adding the CBP and CDC costs, the total cost per investigation event would be $71,092 + $24,614 = $95,706.

TABLE 4—BENEFITS (AVERTED COSTS) PER EVENT IN 2018 USD IN WHICH HUMAN REMAINS WITHOUT ADEQUATE DOCUMENTATION OR SHIPPING CONTAINERS ARE IMPORTED FOR PURPOSES OTHER THAN BURIAL, ENTOMBMENT, OR CREMATION AND ARE HELD AT THE PORT OF ENTRY PENDING AN INVESTIGATION

Agency	Cost components	Hourly wage rate[17]	Multiplier for non-wage benefits and overhead	Total
CDC	600 hours split between GS–13, step 5; GS–14, step 5; and GS–15, step 5 levels.	$59.24	2	$71,092
CBP	300 hours at the GS–5, GS–9, GS–11, GS–12, and GS–15, step 5 level	41.02	2	24,614
Total				95,706

In addition to costs to CDC and CBP, importers of human remains for purposes other than final resting might not use leak-proof containers or fail to provide import permits or importer certification statement(s). When this occurs, importers spend a considerable amount of time communicating with CDC and CBP about missing documentation, searching for missing documentation after those human remains arrive at ports of entry, or repackaging shipments at the importer's expense. This codification of requirements authorized under 42 CFR 71.32(b), 71.54, and 71.55 pertaining to the importation of human remains should reduce confusion. Besides the time spent on searching for documentation and the cost of repackaging, the human remains may begin to decompose during the investigation process, which would affect the value of imports that may otherwise be used for purposes other than final resting. HHS/CDC does not have any way to estimate time for repackaging costs or decomposition costs, and did not receive any public comments on these costs. By reducing confusion, some of these costs may be averted when 42 CFR 71.55 goes into effect. On the other hand, codification of these requirements may increase the costs of human remains for purposes other than burial, entombment, or cremation if such importations are currently occurring without CBP or CDC oversight.

The one-time costs of updating communications materials and the costs for an additional 0.5 importers per year to undergo an inspection to verify their ability to safely import human remains for purposes other than final resting was estimated to cost $46,977 over 10 years (annualized cost: $5,507). These costs can be compared to the benefits (averted costs per investigation after human remains are held at the port of entry because they arrived in a container that was not leak-proof or with improper documentation ($95,706)). During calendar years 2014–2018, there were seven time-intensive investigations for an average 1.4 investigations per year. Among these events, one shipment of human remains was re-exported. The remaining six shipments all required repackaging and were held by CBP for between 2 days and 22 days (average hold: 11.3 days). Of the seven total investigations, six involved human remains imported for purposes other than final resting. One of these shipments was re-exported and the other five shipments of human remains were cremated after being held by CBP. Four of the seven investigations occurred in 2018, demonstrating an increasing trend in improperly imported human remains.

A comparison can be made between the estimated costs and potential benefits (*i.e.,* averted federal government costs for an investigation). This comparison suggests that even if only one held importation requiring investigation will be averted in the 10 years after the codification goes into effect, the expected benefits (averted costs) would exceed expected costs assuming a discount rate of 3% per year. To the extent that this Final Rule would increase the number of inspections by DSAT, the need to conduct investigations should decrease proportionately. This is because it is assumed that the need for investigations results from lack of awareness of importation requirements for human remains for purposes other than final resting as authorized under existing 42 CFR 71.32(b), 71.54 and 71.55. However, the inspection process itself should allow importers to fully

[15] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

[16] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

[17] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

understand their import requirements in regard to shipping containers, documentation, or permits.

In addition to the reduced costs associated with imported human remains for purposes other than burial, entombment, or cremation arriving with inadequate documentation or shipping containers, there may be additional savings for the small numbers of human remains that arrive with insufficient documentation for burial, entombment, or cremation. During calendar years 2014 through 2018, CDC requested additional documentation from seven importers of human remains for burial, entombment or cremation (average 1.4 events per year) and 9 importers of human remains for purposes other than final resting (1.8 events per year). In contrast to the time-intensive investigation events described above, these events were usually resolved quickly because death certificates listing cause of death or importer certification statements either confirming that the human remains were not known to contain or stating why the human remains were not reasonably suspected of containing an infectious biological agent were provided relatively quickly. However, delays still incur some additional time costs that may be averted if the requirements codified in 42 CFR 71.55 are better understood.

Finally, the language in 42 CFR 71.55(d) indicating that 42 CFR 71.63 may apply to imported human remains, if the Director designates a foreign country and determines that such an action is necessary to protect the public health, is cross-referencing an the existing requirement in 42 CFR 71.63. Since its enactment, CDC has applied 42 CFR 71.63 one time, on May 10, 2019, to suspend entry of dogs from Egypt after three dogs with canine rabies virus variant were imported into the United States within four years.[18] However, the suspension has not been in place long enough to do a full economic analysis and a suspension of imports for dogs may not be analogous to a suspension of imports for human remains in terms of economic impact.

B. Executive Order 13771

Executive Order 13771 ''Reducing Regulation and Controlling Regulatory Costs,'' requires executive departments and agencies to eliminate at least two existing regulations for every new significant regulation that imposes costs. HHS/CDC has determined that this rule imposes no more than de minimis costs, and therefore not considered a regulatory action.

C. The Regulatory Flexibility Act

HHS/CDC has analyzed the impacts of the Final Rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). Unless we certify that the Final Rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Based on our analysis as described above, we certify that this Final Rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

This regulatory action is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This Final Rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

D. The Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection requests titled Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920–0134) and 0920–0199 Application for Permit to Import Biological Agents and Vectors of Human Disease into the United States and Application for Permit to Import or Transport Live Bats (42 CFR 71.54) (expiration date 04/30/2021) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a Notice of Proposed Rulemaking on November 25, 2019 to obtain comments from the public and affected agencies. CDC received no comments related to the previous document. This document 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 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this document 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 final rule publication.

HHS/CDC currently has approval to collect certain information concerning the importation of dead bodies under two OMB Control Numbers: 0920–0134 *Foreign Quarantine Regulations* (expiration date 03/31/2022) and 0920–0199 Application for Permit to Import Biological Agents and Vectors of Human Disease into the United States and Application for Permit to Import or Transport Live Bats (42 CFR 71.54) (expiration date 04/30/2021). This Final Rule is updating one information collection: 0920–0134. CDC invited public comment on the burden to the public outlined in the NPRM and did not receive any comments.

Information Collections

(1) Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920–0134)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Description

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) authorizes the Secretary of Health and

[18] CDC (May 10, 2019) Notice of Temporary Suspension of Dogs Entering the United States From Egypt. 84 FR 20628. *https://www.federalregister.gov/documents/2019/05/10/2019-09654/notice-of-temporary-suspension-of-dogs-entering-the-united-states-from-egypt.*

Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Legislation and existing regulations governing foreign and interstate quarantine activities (42 CFR parts 70 and 71) authorize CDC quarantine officers and customs personnel to inspect and undertake necessary control measures in order to protect the public's health. Other inspection agencies assist quarantine officers in public health risk assessment and management of persons, animals, and other importations of public health importance, including human remains. Human remains may harbor communicable diseases, and if not packaged and processed according to accepted standards, may represent a risk to handlers and the receiving community.

Requiring a death certificate that states the cause of death (or a specified alternative document) and requiring appropriate packaging of human remains mitigates the introduction and spread of communicable diseases into the United States with a minimum of recordkeeping and reporting as well as a minimum of interference with trade and travel. The death certificate will only be required for those seeking to import human remains that have not been embalmed or otherwise rendered noninfectious.

- At present, HHS/CDC has approval from OMB to collect certain information and impose recordkeeping requirements related to foreign quarantine responsibilities under OMB Control Number 0920–0134 (expiration 03/31/2022). HHS/CDC is proposing a non-substantive/nonmaterial change to:
- 42 CFR 71.55 Dead Bodies, 42 CFR 71.32(b)—Death certificates (No Form)
- 42 CFR 71.32 Statements or documentation of non-infectiousness (No Form)

Description of Respondents. Respondents to this data collection are individuals seeking to import human remains into the United States.

There is no burden to respondents other than the time taken to acquire a death certificate for the human remains being imported to the United States or to produce documentation stating that the human remains have been embalmed or otherwise rendered non-infectious. However, death certificates and embalming documentation are routinely produced by mortuary providers or hospitals after a death. DOS also provides a consular mortuary certificate that also commonly states the cause of death for an individual who dies abroad or, if the cause of death is not known, can reference whether the person died of a communicable disease. HHS/CDC does not anticipate significant additional administrative burden in acquiring these documents.

With data provided by CBP, CDC is updating the estimate of the number of imports of human remains that will require a death certificate from 20 to 150, and increasing by 1850 the estimate of the number of human remains that will require some statement or documentation of non-infectiousness. CDC believes this is a more accurate estimate of the volume of imported human remains imported into the United States, and not an increase in respondent burden. As stated above, both of these documents are routinely provided by mortuary services and do not represent an increase in respondent burden specifically for this rulemaking.

Additionally, as this Final Rule clarifies the requirements for importing human remains, HHS/CDC is also renaming the provision. The associated information collections will clearly reference the title:

- 42 CFR 71.55 Importation of Human Remains—Death Certificate (No Form).
- 42 CFR 71.32, 71.55 Statements or documentation of non-infectiousness (No Form).

Table 5 below presents the estimate of annual burden (in hours) associated with the reporting requirement under this OMB control number, accounting for the rule changes.

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN 0920–0134

Type of respondent	Regulatory provision or form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Importers	42 CFR 71.55 Importation of Human Remains—Death Certificate (No Form).	150	1	1	150
Importer	42 CFR 71.32, 71.55 Statements or documentation of non-infectiousness (No Form).	3850	1	5/60	321

The estimates are based on experience to date with current recordkeeping and reporting requirements of 42 CFR 71.55 Dead Bodies—Death Certificate (No Form) and 42 CFR 71.32 Statements or documentation of non-infectiousness, are based on discussion with partners at DOS and DHS.

(2) Application for Permit to Import Biological Agents and Vectors of Human Disease into the United States and Application for Permit to Import or Transport Live Bats (42 CFR 71.54) (OMB Control No. 0920–0199) No Change Requested–Center for Preparedness and Response, Centers for Disease Control and Prevention.

CDC/DSAT administers OMB Control No. 0920–0199 and did not make any changes in information collection. Due to DSAT's experience with issuing CDC import permits, DSAT does not expect any additional burden from respondents because respondents understand that any material including human remains that is reasonably suspected of containing an infectious biological agent requires submission of an application for CDC import permit.

On an annual basis, DSAT usually receives approximately 3 applications for importing human remains that are known to contain or reasonably suspected of containing an infectious biological agent. DSAT performs inspection of these requests to ensure that the facility has the appropriate biosafety conditions to receive these materials. DSAT plans to use current resources for processing any applications received for importing human remains that are known to contain or reasonably suspected of containing an infectious biological agent.

E. Executive Order 12866

This rule is not being treated as a significant regulatory action as defined by Executive Order 12866. As such, it

has not been reviewed by the Office of Management and Budget (OMB).

F. National Environmental Policy Act (NEPA)

HHS/CDC has determined that the amendments to 42 CFR part 71 will not have a significant impact on the human environment.

G. Executive Order 12988: Civil Justice Reform

HHS/CDC has reviewed this rule under Executive Order 12988 on Civil Justice Reform and determines that this Final Rule meets the standard in the Executive Order.

H. Executive Order 13132: Federalism

Under Executive Order 13132, a Federalism analysis is required if a rulemaking has Federalism implications, would limit or preempt State or local law, or impose substantial direct compliance costs on State or local governments. Under such circumstances, a Federal agency must consult with State and local officials. Federalism implications is defined as having substantial direct effects on State or local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under 42 U.S.C. 264(e), Federal public health regulations promulgated under that section do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal Government and State/local governments as set forth in 42 U.S.C. 264. There are no provisions in these regulations that impose direct compliance costs on State and local governments. Therefore, HHS/CDC believes that the rule does not warrant additional consultation under Executive Order 13132.

I. The Plain Language Act of 2010

Under the Plain Language Act of 2010 (Pub. L. 111–274, October 13, 2010), Executive Departments and Agencies are required to use plain language in all proposed and Final Rules. Prior to publication, this Final Rule was reviewed by specialists in health communication and education to ensure the content and intention, as well as substance, were clear and accurate. HHS/CDC did not receive any public comment concerning plain language.

List of Subjects in 42 CFR Part 71

Burial, communicable diseases, cremation, death certificate, entombment, human remains, importer, infectious biological agent, leak-proof container, public health, quarantinable communicable diseases.

For the reasons discussed in the preamble, we amend 42 CFR part 71 as follows:

PART 71—FOREIGN QUARANTINE

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

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); secs. 361–369, PHS Act, as amended (42 U.S.C. 264–272).

■ 2. Amend § 71.50, paragraph (b), by adding in alphabetical order definitions for ''Death certificate'', ''Human remains'', ''Importer'', and ''Leak-proof container'' to read as follows:

§ 71.50 Scope and definitions.

* * * * *

(b) * * *

Death certificate means an official government document that certifies that a death has occurred and provides identifying information about the deceased, including (at a minimum) name, age, and sex. The document must also certify the time, place, and cause of death (if known). If the official government document is not written in English, then it must be accompanied by an English language translation of the official government document, the authenticity of which has been attested to by a person licensed to perform acts in legal affairs in the country where the death occurred. In lieu of a death certificate, a copy of the Consular Mortuary Certificate and the Affidavit of Foreign Funeral Director and Transit Permit, shall together constitute acceptable identification of human remains.

* * * * *

Human remains means a deceased human body or any portion of a deceased human body, except:

(i) Clean, dry bones or bone fragments; human hair; teeth; fingernails or toenails; or

(ii) A deceased human body and portions thereof that have already been fully cremated prior to import; or

(iii) Human cells, tissues or cellular or tissue-based products intended for implantation, transplantation, infusion, or transfer into a human recipient.

Importer means any person importing or attempting to import an item regulated under this subpart.

* * * * *

Leak-proof container means a container that is puncture-resistant and sealed in such a manner as to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping, such as

(i) A double-layered plastic, puncture-resistant body bag (*i.e.,* two sealed body bags, one inside the other);

(ii) A casket with an interior lining certified by the manufacturer to be leak-proof and puncture-resistant; or

(iii) A sealed metal body-transfer case.

* * * * *

■ 3. Revise § 71.55 to read as follows:

§ 71.55 Importation of human remains.

(a) Human remains imported into the United States, or in transit within the United States and not intended for import, must be fully contained within a leak-proof container that is packaged and shipped in accordance with all applicable legal requirements.

(b) The provisions of 42 CFR 71.54 shall apply to all imported human remains known to contain or reasonably suspected of containing an infectious biological agent.

(c) Unless accompanied by a permit issued under 42 CFR 71.54, human remains imported into the United States must meet one of the following requirements:

(1) Human remains imported for burial, entombment, or cremation must:

(i) Be consigned directly to a licensed mortuary, cemetery, or crematory for immediate and final preparation prior to burial, entombment, or cremation; and

(ii) Unless embalmed, be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

(2) Human remains imported for medical examination or autopsy must:

(i) Be consigned directly to an entity authorized to perform such functions under the laws of the applicable jurisdiction prior to subsequent burial, entombment, or cremation; and

(ii) Unless embalmed, be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

(3) Human remains imported for any other purpose, unless embalmed, must be accompanied by an importer

certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

(d) The Director may suspend the importation of human remains under 42 CFR 71.63 if the Director designates the foreign country and determines that such an action is necessary to protect the public health.

Dated: June 3, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–12931 Filed 7–14–20; 8:45 am]

BILLING CODE 4163–18–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 76

[MB Docket Nos. 19–165, 17–105; FCC 20–8; FRS 16923]

Electronic Delivery of Notices to Broadcast Television Stations; Modernization of Media Regulation Initiative

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of compliance date.

SUMMARY: In this document, the Federal Communications Commission (FCC) announces that the Office of Management and Budget (OMB) has approved non-substantive and non-material changes to the information collections associated with certain rule amendments adopted in the Report and Order, FCC 20–8, MB Docket Nos. 19–165, 17–105 (*Report and Order),* to modernize certain notice requirements for cable operators and direct broadcast satellite (DBS) providers. The Commission also announces that compliance with the revised rules is required. This document is consistent with *Electronic Delivery of Notices to Broadcast Television Stations,* published March 20, 2020, which stated that the Commission would publish a document in the **Federal Register** announcing the compliance date for the revised rules listed in the **DATES** section below.

DATES: Compliance with the amendments to 47 CFR 74.779, 76.54(e), 76.64(k), 76.66(d)(1)(vi), (d)(2)(ii), (v), and (vi), (d)(3)(iv), (d)(5)(i), (f)(3) and (4), and (h)(5), 76.1600(e), 76.1607, 76.1608, 76.1609, and 76.1617(a) and (c), published March 20, 2020, at 85 FR 15999, is required as of July 31, 2020.

FOR FURTHER INFORMATION CONTACT: Brendan Holland of the Media Bureau, Industry Analysis Division, at (202) 418–2757 or *Brendan.Holland@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that OMB approved the non-substantive and non-material changes to the information collection requirements in §§ 76.1607 and 76.1617(a) and (c) on March 19, 2020. OMB approved the non-substantive and non-material changes to the information collection requirements in §§ 76.54(e), 76.64(k), 76.66(d)(1)(vi), (d)(2)(ii), (v), and (vi), (d)(3)(iv), (d)(5)(i), (f)(3) and (4), and (h)(5), 76.1600(e), 76.1607, and 76.1608 on March 31, 2020, and the changes to § 76.1609 were approved by OMB on April 13, 2020. The remaining rule amendments adopted in the *Report and Order* did not contain new or modified information collection requirements subject to OMB approval under the Paperwork Reduction Act.

The Commission publishes this document as an announcement of the compliance date of the revised rules. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street SW, Washington, DC 20554, regarding OMB Control Number 3060–1273. Please include the applicable OMB Control Number in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received final OMB approval for the information collection requirements contained in §§ 76.54(e), 76.64(k), 76.66(d)(1)(vi), (d)(2)(ii), (v), and (vi), (d)(3)(iv), (d)(5)(i), (f)(3) and (4), and (h)(5), 76.1600(e), 76.1607, 76.1608, 76.1609, and 76.1617(a) and (c). Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number.

The foregoing is required by the Paperwork Reduction Act of 1995, Pub. L. 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0311.

OMB Approval Date: March 31, 2020.

OMB Expiration Date: March 31, 2023.

Title: Section 76.54, Significantly Viewed Signals; Method to be Followed for Special Showings.

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 500 respondents; 1,274 responses.

Estimated Time per Response: 1–15 hours (average).

Frequency of Response: On-occasion reporting and third-party disclosure requirements.

Total Annual Burden: 20,610 hours.

Total Annual Cost: $300,000.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act: No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 76.54(b) state significant viewing in a cable television or satellite community for signals not shown as significantly viewed under 47 CFR 76.54(a) or (d) may be demonstrated by an independent professional audience survey of over-the-air television homes that covers at least two weekly periods separated by at least thirty days but no more than one of which shall be a week between the months of April and September. If two surveys are taken, they shall include samples sufficient to assure that the combined surveys result in an average figure at least one standard error above the required viewing level.

The information collection requirements contained in 47 CFR 76.54(c) are used to notify interested parties, including licensees or permittees of television broadcast stations, about audience surveys that are being conducted by an organization to demonstrate that a particular broadcast station is eligible for significantly viewed status under the Commission's rules. The notifications provide interested parties with an opportunity to review survey methodologies and file objections.

Lastly, 47 CFR 76.54(e) and (f), are used to notify television broadcast

stations about the retransmission of significantly viewed signals by a satellite carrier into these stations' local market.

The FCC received approval from OMB for a non-substantive and non-material change to the information collection under OMB Control No. 3060–0311 as a result of the rulemaking discussed below.

On January 30, 2020, the Commission adopted a Report and Order, FCC 20–8, in MB Docket Nos. 19–165 and 17–105 (*Report and Order*). The *Report and Order* updated the Commission's notification rules for cable operators and direct broadcast satellite providers by transitioning certain written notices from paper to electronic delivery via email. To help effectuate this transition to email delivery of notices, the *Report and Order* revised 47 CFR 76.54(e) to require that after July 31, 2020, the notices mandated by the rule must be delivered to television broadcast stations electronically in accordance with 47 CFR 76.66(d)(2)(ii). The revised requirements are effective as stated in the summary of the *Report and Order,* published at 85 FR 15999, on March 20, 2020.

OMB Control Number: 3060–0419.

OMB Approval Date: April 13, 2020.

OMB Expiration Date: March 31, 2023.

Title: Sections 76.94, Notification; 76.95, Exceptions, 76.105, Notification; 76.106, Exceptions; 76.107, Exclusivity contracts; and 76.1609, Non duplication and syndicated exclusivity.

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 5,977 respondents; 249,577 responses.

Estimated Time per Response: 0.5 to 2.0 hours.

Frequency of Response: On-occasion reporting requirement; One-time reporting requirement; Third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in Section 4(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 233,153 hours.

Total Annual Cost: No cost.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act: No impact(s).

Needs and Uses: The Commission rules that are covered under this collection require broadcast television stations and program distributors to notify cable television system operators of network non-duplication protection and syndicated exclusivity rights being sought within prescribed limitations and terms of contractual agreements. These various notification and disclosure requirements are to protect broadcasters who purchase the exclusive rights to transmit network and syndicated programming in their recognized markets. The FCC received approval from OMB for a non-substantive and non-material change to the information collection under OMB Control No. 3060–0419 as a result of the rulemaking discussed below.

On January 30, 2020, the Commission adopted a Report and Order, FCC 20–8, in MB Docket Nos. 19–165 and 17–105 (*Report and Order*). The *Report and Order* updated the Commission's notification rules for cable operators and direct broadcast satellite providers by transitioning certain written notices from paper to electronic delivery via email. To help effectuate this transition to email delivery of notices, the *Report and Order* revised 47 CFR 76.1609 to require that after July 31, 2020, the notices mandated by the rule must be delivered to broadcast stations electronically in accordance with 47 CFR 76.1600. The revised requirements are effective as stated in the summary of the *Report and Order,* published at 85 FR 15999, on March 20, 2020.

OMB Control Number: 3060–0649.

OMB Approval Date: March 19, 2020.

OMB Expiration Date: February 28, 2023.

Title: Section 76.1601, Deletion or Repositioning of Broadcast Signals; Section 76.1617, Initial Must-Carry Notice; Section 76.1607, Principal Headend.

Form Number: N/A.

Respondents: Business or other for-profit entities; Not for profit institutions.

Number of Respondents and Responses: 3,300 respondents; 3,950 responses.

Estimated Time per Response: 0.5 to 1.0 hours.

Frequency of Response: On-occasion reporting requirement; Third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in Section 4(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 2,050 hours.

Total Annual Cost: No cost.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act: No impact(s).

Needs and Uses: The information collection requirements covered under this information collection are as follows:

Regulations at 47 CFR 76.1601 require that a cable operator shall provide written notice to any broadcast television station at least 30 days prior to either deleting from carriage or repositioning that station. Such notification shall also be provided to subscribers of the cable system.

Regulations at 47 CFR 76.1607 require that a cable operator shall provide written notice to all stations carried on its system pursuant to the must-carry rules at least 60 days prior to any change in the designation of its principal headend.

Regulations at 47 CFR 76.1617(a) state within 60 days of activation of a cable system, a cable operator must notify all qualified Non-Commercial Education (NCE) stations of its designated principal headend.

Regulations at 47 CFR 76.1617(b) state within 60 days of activation of a cable system, a cable operator must notify all local commercial and NCE stations that may not be entitled to carriage because they either fail to meet the standards for delivery of a good quality signal to the cable system's principal headend, or may cause an increased copyright liability to the cable system.

Regulations at 47 CFR 76.1617(c) state within 60 days of activation of a cable system, a cable operator must send a list of all broadcast television stations carried by its system and their channel positions to all local commercial and noncommercial television stations, including those not designated as must-carry stations and those not carried on the system.

The FCC received approval from OMB for a non-substantive and non-material change to the information collection under OMB Control No. 3060–0649 as a result of the rulemaking discussed below.

On January 30, 2020, the Commission adopted a Report and Order, FCC 20–8, in MB Docket Nos. 19–165 and 17–105 (*Report and Order*). The *Report and Order* updated the Commission's notification rules for cable operators and direct broadcast satellite providers by transitioning certain written notices from paper to electronic delivery via email. To help effectuate this transition to email delivery of notices, the *Report and Order* revised 47 CFR 76.1601, 76.1607, and 76.1617 to require that after July 31, 2020, the notices mandated by these rules must be delivered to broadcast stations electronically in accordance with 47 CFR 76.1600. The revised requirements are effective as stated in the summary of

the *Report and Order,* published at 85 FR 15999, on March 20, 2020.

OMB Control Number: 3060–0652.

OMB Approval Date: March 31, 2020.

OMB Expiration Date: June 30, 2023.

Title: Section 76.309, Customer Service Obligations; Section 76.1600, Electronic Delivery of Notices; Section 76.1602, Customer Service—General Information, Section 76.1603, Customer Service—Rate and Service Changes and 76.1619, Information and Subscriber Bills.

Form Number: N/A.

Respondents: Business or other for-profit entities; State, Local or Tribal Government.

Number of Respondents and Responses: 4,113 respondents; 1,109,246 responses.

Estimated Time per Response: 0.0167 to 1.0 hours.

Frequency of Response: On-occasion reporting requirement; Third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in Sections 4(i) and 632 of the Communications Act of 1934, as amended.

Total Annual Burden: 41,796 hours.

Total Annual Cost: No cost.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act: No impact(s).

Needs and Uses: The Commission requires that the various disclosure and notifications contained in this collection as a means of consumer protection to ensure that subscribers and franchising authorities are aware of cable operators' business practices, current rates, rate changes for programming, service and equipment, and channel line-up changes. Permitting the use of email modernizes the Commission's rules regarding notices required to be provided by MVPDs. The FCC received approval from OMB for a non-substantive and non-material change to the information collection under OMB Control No. 3060–0652 as a result of the rulemaking discussed below.

On January 30, 2020, the Commission adopted a Report and Order, FCC 20–8, in MB Docket Nos. 19–165 and 17–105 (*Report and Order*). The *Report and Order* updated the Commission's notification rules for cable operators and direct broadcast satellite providers by transitioning certain written notices from paper to electronic delivery via email. To help effectuate this transition to email delivery of notices, the *Report and Order* added to 47 CFR 76.1600 a new subsection (e) requiring that after July 31, 2020, cable operators must use email to deliver the notices required by §§ 76.64(k), 76.1601, 76.1607, 76.1608, 76.1609, and 76.1617 to broadcast television stations.

Specifically, after July 31, 2020, covered notices to full-power and Class A television stations must be emailed to the ''carriage issues'' inbox that the station publicizes in its online public inspection file (OPIF) in accordance with 47 CFR 73.3526 and 73.3527. Similarly, after July 31, 2020, covered notices to low-power television (LPTV) stations will be emailed to the inbox already provided by the station licensee in the Commission's Licensing and Management System (LMS) under existing procedures. After July 31, 2020, covered notices to qualified noncommercial educational (NCE) translator stations must be delivered to the email address listed for the licensee of the NCE translator station in LMS, or alternatively to the ''carriage issues'' email address listed in the primary station's OPIF, if the NCE translator station does not have its own email address listed in LMS. The revised requirements are effective as stated in the summary of the *Report and Order,* published at 85 FR 15999, on March 20, 2020.

OMB Control Number: 3060–0844.

OMB Approval Date: March 31, 2020.

OMB Expiration Date: February 28, 2023.

Title: Cable Carriage of Television Broadcast Stations: Section 76.56(a) Carriage of qualified noncommercial educational stations; Section 76.57, Channel positioning; Section 76.61(a)(1)–(2) Section 76.64, Retransmission consent.

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 4,902 respondents; 7,082 responses.

Estimated Time per Response: 0.5 to 5.0 hours.

Frequency of Response: On-occasion reporting requirement; Third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in Sections 1, 4(i) and (j), 325, 338, 614, 615, 631, 632, and 653 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i) and (j), 325, 338, 534, 535, 551, 552, and 573.

Total Annual Burden: 4,486 hours.

Total Annual Cost: No cost.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act: No impact(s).

Needs and Uses: Under Section 614 of the Communications Act and the implementing rules adopted by the Commission, commercial TV broadcast stations are entitled to assert mandatory carriage rights on cable systems located within the station's television market. Under Section 325(b) of the Communications Act, commercial TV broadcast stations are entitled to negotiate with local cable systems for carriage of their signal pursuant to retransmission consent agreements in lieu of asserting must carry rights. This system is therefore referred to as ''Must-Carry and Retransmission Consent.'' Under Section 615 of the Communications Act, noncommercial educational (NCE) stations are also entitled to assert mandatory carriage rights on cable systems located within the station's market; however, noncommercial TV broadcast stations are not entitled to retransmission consent. The Commission's rules implementing sections 614 and 615 of the Communications Act require, among other things, that a cable system commencing new operation must notify all local commercial and noncommercial broadcast stations of its intent to commence service. The cable operator must send such notification at least 60 days prior to commencing cable service (New Cable System Notices). The new cable system must notify each station if its signal quality does not meet the standards for carriage and if any copyright liability would be incurred for the carriage of such signal. The FCC received approval from OMB for a non-substantive and non-material change to the information collection under OMB Control No. 3060–0844 as a result of the rulemaking discussed below.

On January 30, 2020, the Commission adopted a Report and Order, FCC 20–8, in MB Docket Nos. 19–165 and 17–105 (*Report and Order*). The *Report and Order* updated the Commission's notification rules for cable operators and direct broadcast satellite providers by transitioning certain written notices from paper to electronic delivery via email. To help effectuate this transition to email delivery of notices, the Report and Order revised 47 CFR 76.64(k) to require that after July 31, 2020, the New Cable System Notices mandated by the rule must be delivered to broadcast stations electronically in accordance with 47 CFR 76.1600. The revised requirements are effective as stated in the summary of the *Report and Order,* published at 85 FR 15999, on March 20, 2020.

OMB Control Number: 3060–0980.

OMB Approval Date: March 31, 2020.

OMB Expiration Date: February 28, 2023.

Title: Implementation of the Satellite Home Viewer Extension and Reauthorization Act of 1999: Local Broadcast Signal Carriage Issues and Retransmission Consent Issues—47 CFR Section 76.66.

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 3,410 respondents; 4,388 responses.

Estimated Time per Response: 0.5 to 5.0 hours.

Frequency of Response: On-occasion reporting requirement; Third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in 47 U.S.C. 325, 338, 339, and 340.

Total Annual Burden: 3,576 hours.

Total Annual Cost: $24,000.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act: No impact(s).

Needs and Uses: On January 30, 2020, the Commission adopted a Report and Order, FCC 20–8, in MB Docket Nos. 19–165 and 17–105 (*Report and Order*). The *Report and Order* updated the Commission's notification rules for cable operators and direct broadcast satellite (DBS) providers by transitioning certain written notices from paper to electronic delivery via email. To help effectuate this transition to email delivery of notices, the *Report and Order* revised 47 CFR 76.66(d)(1)(vi), (d)(2)(i), (d)(2)(v), (d)(2)(vi), (d)(3)(iv), (d)(5)(i), (f)(3)–(4), and (h)(5) to require that after July 31, 2020, the notices mandated by these rules must be delivered to television broadcast stations electronically in accordance with 47 CFR 76.66(d)(ii). That rule, as revised by the *Report and Order,* requires that after July 31, 2020, covered notices to television broadcast stations must be emailed to the ''carriage issues'' inbox that the station publicizes in its online public inspection file (OPIF) in accordance with 47 CFR 73.3526 and 73.3527. The revised requirements are effective as stated in the summary of the *Report and Order,* published at 85 FR 15999, on March 20, 2020.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2020–14960 Filed 7–14–20; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 85, No. 136
Wednesday, July 15, 2020

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0582; Product Identifier 2020–NM–059–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2014–26–07 and AD 2019–07–01 which apply to Dassault Aviation Model FAN JET FALCON and FAN JET FALCON SERIES C, D, E, F, and G airplanes. AD 2019–07–01 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations and maintenance requirements. Since the FAA issued AD 2019–07–01, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 31, 2020.

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

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

For EASA material identified in this proposed AD that will be incorporated by reference (IBR), contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.*

For the Dassault material identified in this proposed AD that will continue to be incorporated by reference, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *https://www.dassaultfalcon.com.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0582.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0582; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226; email *tom.rodriguez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–0582; Product Identifier 2020–NM–059–AD'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this NPRM based on 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 that are received, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact the FAA receives about this NPRM.

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 NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA issued AD 2019–07–01, Amendment 39–19612 (84 FR 16390, April 19, 2019) (''AD 2019–07–01''), for certain Dassault Aviation Model FAN JET FALCON and FAN JET FALCON SERIES C, D, E, F, and G airplanes. AD 2019–07–01 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations and maintenance requirements. AD 2019–07–01 resulted from a determination of the need for a revision to the airplane airworthiness limitations to introduce changes to the maintenance requirements and airworthiness limitations. The FAA issued AD 2019–07–01 to address, among other things, fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane.

AD 2019–07–01 specifies that accomplishing the revision required by paragraph (g) of that AD terminates all requirements of AD 2014–26–07, Amendment 39–18058 (80 FR 2815, January 21, 2015) (''AD 2014–26–07'').

Actions Since AD 2019–07–01 Was Issued

Since the FAA issued AD 2019–07–01, the FAA has determined that new or more restrictive airworthiness limitations are necessary.

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0141, dated June 17, 2019 (''EASA AD 2019–0141'') (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Dassault Aviation Model FAN JET FALCON and FAN JET FALCON SERIES C, D, E, F, and G airplanes.

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is proposing this AD to address, among other things, fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane. See the MCAI for additional background information.

Related IBR Material Under 1 CFR Part 51

EASA AD 2019–0141 describes new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This AD would also require Chapter 5–40, Airworthiness Limitations, DGT 131028, Revision 17, dated September 2017, of the Dassault Aviation Falcon 20 Maintenance Manual, which the Director of the Federal Register approved for incorporation by reference as of May 24, 2019 (84 FR 16390, April 19, 2019).

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

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA has evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Proposed AD Requirements

This proposed AD would retain the requirements of AD 2019–07–01. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, which are specified in EASA AD 2019–0141 described previously, as incorporated by reference. Any differences with EASA AD 2019–0141 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (l)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2019–0141 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2019–0141 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in the EASA AD.

Service information specified in EASA AD 2019–0141 that is required for compliance with EASA AD 2019–0141 will be available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0582 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c).

Costs of Compliance

The FAA estimates that this proposed AD affects 168 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from

AD 2019–07–01 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. In the past, the agency has estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. The FAA estimates the total cost per operator for the new proposed actions to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2014–26–07, Amendment 39–18058 (80 FR 2815, January 21, 2015); and AD 2019–07–01, Amendment 39–19612 (84 FR 16390, April 19, 2019); and

■ b. Adding the following new AD:

Dassault Aviation: Docket No. FAA–2020–0582; Product Identifier 2020–NM–059–AD.

(a) Comments Due Date

The FAA must receive comments by August 31, 2020.

(b) Affected ADs

This AD replaces AD 2014–26–07, Amendment 39–18058 (80 FR 2815, January 21, 2015) (''AD 2014–26–07''); and AD 2019–07–01, Amendment 39–19612 (84 FR 16390, April 19, 2019) (''AD 2019–07–01'').

(c) Applicability

This AD applies to the Dassault Aviation airplanes specified in paragraphs (c)(1) and (2) of this AD, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2019–0141, dated June 17, 2019 (''EASA AD 2019–0141'').

(1) Model FAN JET FALCON airplanes.

(2) Model FAN JET FALCON SERIES C, D, E, F, and G airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address, among other things, fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Maintenance or Inspection Program Revision, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2019–07–01, with no changes. Within 12 months after May 24, 2019 (the effective date of AD 2019–07–01), revise the existing maintenance or inspection program, as applicable, to incorporate the airworthiness limitations and maintenance requirements specified in Chapter 5–40, Airworthiness Limitations, DGT 131028, Revision 17, dated September 2017, of the Dassault Aviation Falcon 20 Maintenance Manual. The initial compliance time for accomplishing the actions is at the applicable time specified in Chapter 5–40, Airworthiness Limitations, DGT 131028, Revision 17, dated September 2017, of the Dassault Aviation Falcon 20 Maintenance Manual or within 12 months after May 24, 2019, whichever occurs later. Where the threshold column in the table in paragraph B, Mandatory Maintenance Operations, of Chapter 5–40, Airworthiness Limitations, DGT 131028, Revision 17, dated September 2017, of the Dassault Aviation Falcon 20 Maintenance Manual specifies a compliance time in years, those compliance times are since the date of issuance of the original French or EASA airworthiness certificate or date of issuance of the original French or EASA export certificate of airworthiness. Accomplishing the maintenance or inspection program revision required by paragraph (i) of this AD terminates the requirements of this paragraph.

(h) Retained Restrictions on Alternative Actions and Intervals With a New Exception

This paragraph restates the requirements of paragraph (h) of AD 2019–07–01, with a new exception. Except as required by paragraph (i) of this AD, after accomplishing the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l)(1) of this AD.

(i) New Maintenance or Inspection Program Revision

Except as specified in paragraph (j) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2019–0141. Accomplishing the maintenance or inspection program revision required by this paragraph terminates the requirements of paragraph (g) of this AD.

(j) Exceptions to EASA AD 2019–0141

(1) The requirements specified in paragraphs (1), (2), (4), and (5) of EASA AD 2019–0141 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2019–0141 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, to incorporate the ''limitations, tasks and associated thresholds and intervals'' specified in paragraph (3) of EASA AD 2019–0141 within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2019–0141 is at the applicable ''associated thresholds'' specified in paragraph (3) of EASA AD 2019–0141, or within 90 days after the effective date of this AD, whichever occurs later.

(4) The ''Remarks'' section of EASA AD 2019–0141 does not apply to this AD.

(k) New Provisions for Alternative Actions and Intervals

After the maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed except as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2019–0141.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (m)(4) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.*

(i) 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.

(ii) AMOCs approved previously for AD 2019–07–01 are approved as AMOCs for the corresponding provisions of EASA AD 2019–0141 that are required by paragraph (g) of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Related Information

(1) For information about EASA AD 2019–0141, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu;* Internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(2) For information about the Dassault material identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *https://www.dassaultfalcon.com.*

(3) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0582.

(4) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226; email *tom.rodriguez@faa.gov.*

Issued on July 8, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–15126 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0580; Product Identifier 2020–NM–052–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2019–02–03, which applies to all The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. AD 2019–02–03 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2019–02–03, the manufacturer has developed a new fire handle design that will eliminate the need for the airworthiness limitations required by AD 2019–02–03. This proposed AD would retain the requirements of AD 2019–02–03 and would require incorporation of an airworthiness limitation which applies only to certain airplanes. This proposed AD would also require replacing or modifying certain engine fire control panels, which would terminate the revised airworthiness limitation when a certain condition is met. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 31, 2020.

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 NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0580.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0580; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tak Kobayashi, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3553; email: *takahisa.kobayashi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–0580; Product Identifier 2020–NM–052–AD'' at the beginning of your comments. The FAA

specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM because of those comments.

The FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this proposed AD.

Discussion

The FAA issued AD 2019–02–03, Amendment 39–19550 (84 FR 2437, February 7, 2019) (''AD 2019–02–03''), for all The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. AD 2019–02–03 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. AD 2019–02–03 resulted from reports of warpage of internal engine fire handle components, which can cause binding and prevent proper operation. The FAA issued AD 2019–02–03 to address a latent failure of the engine fire handle, which could result in the inability to extinguish an engine fire that, if uncontrollable, could lead to wing failure.

Actions Since AD 2019–02–03 Was Issued

The preamble to AD 2019–02–03 explains that the FAA considered the requirements ''interim action'' and was considering further rulemaking. Since the FAA issued AD 2019–02–03, the manufacturer developed a new fire handle design for the engine fire control panel. The FAA has determined that replacement with a new or modified engine fire control panel addresses the unsafe condition and will eliminate the need for the airworthiness limitations required by AD 2019–02–03. Therefore, the FAA has determined that the airworthiness limitations required by AD 2019–02–03 should be revised to limit its applicability to airplanes equipped with the old design—an engine fire control panel having part number (P/N) 412600–001 or an engine fire shutoff switch having P/N 417000–101 or 417000–102. The FAA has also determined that once the new or modified engine fire control panel is installed on all affected airplanes in an operator's fleet, the revised airworthiness limitation may be removed.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Requirements Bulletin B787–81205–SB260008–00 RB, Issue 001, dated March 10, 2020. The service information describes procedures for replacing the engine fire control panel with a new or modified panel. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would retain all actions of AD 2019–02–03. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate an airworthiness limitation that applies to airplanes equipped with an engine fire control panel having part number (P/N) 412600–001, or an engine fire shutoff switch having P/N 417000–101 or P/N 417000–102. This proposed AD would also require accomplishment of the actions identified in Boeing Requirements Bulletin B787–81205–SB260008–00 RB, Issue 001, dated March 10, 2020, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0580.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (o) of this proposed AD.

Explanation of Requirements Bulletin

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (AD ARC), to enhance the AD system. One enhancement is a process for annotating which steps in the service information are ''required for compliance'' (RC) with an AD. Boeing has implemented this RC concept into Boeing service bulletins.

In an effort to further improve the quality of ADs and AD-related Boeing service information, a joint process improvement initiative was worked between the FAA and Boeing. The initiative resulted in the development of a new process in which the service information more clearly identifies the actions needed to address the unsafe condition in the ''Accomplishment Instructions.'' The new process results in a Boeing Requirements Bulletin, which contains only the actions needed to address the unsafe condition (*i.e.,* only the RC actions).

Costs of Compliance

The FAA estimates that this proposed AD affects 122 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2019–02–03 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. In the past, the agency has estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new proposed maintenance or inspection program revision to be $7,650 (90 work-hours × $85 per work-hour).

ESTIMATED COSTS FOR REQUIRED REPLACEMENT OR MODIFICATION

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement or modification	2 work-hours × $85 per hour = $170	$5,000	$5,170	$630,740

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in our cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that the proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2019–02–03, Amendment 39–19550 (84 FR 2437, February 7, 2019), and adding the following new AD:

The Boeing Company: Docket No. FAA–2020–0580; Product Identifier 2020–NM–052–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by August 31, 2020.

(b) Affected ADs

This AD replaces AD 2019–02–03, Amendment 39–19550 (84 FR 2437, February 7, 2019) (''AD 2019–02–03'').

(c) Applicability

This AD applies to all The Boeing Company Model 787–8, 787–9, and 787–10 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire protection.

(e) Unsafe Condition

This AD was prompted by reports of warpage of internal engine fire handle components that can cause binding and prevent proper operation, and by the development of a new fire handle design that will prevent the unsafe condition. The FAA is issuing this AD to address a latent failure of the engine fire handle, which could result in the inability to extinguish an engine fire that, if uncontrollable, could lead to wing failure.

(f) Compliance

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

(g) Retained Maintenance/Inspection Program Revision, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2019–02–03, with no changes. Within 14 days after February 22, 2019 (the effective date of AD 2019–02–03), revise the existing maintenance or inspection program, as applicable, to add airworthiness limitation 28–AWL–FIRE, by incorporating the information specified in figure 1 to paragraph (g) of this AD into the Airworthiness Limitations Section of the Instructions for Continued Airworthiness. The initial compliance time for accomplishing the actions specified in figure 1 to paragraph (g) of this AD is within 45 days after February 22, 2019.

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Figure 1 to paragraph (g): *Engine fire handle operational check*

AWL No.	Task	Interval	Applicability	Description
28-AWL -FIRE	ALI	30 days	787-8, -9, and -10 airplanes	Engine Fire Handle Operational Check. Concern: The fire handle design can result in airplanes operating with an engine fire handle that cannot be operated. A latently failed engine fire handle could prevent the fire extinguishing agent from being able to be released. In the event of certain engine fires, the potential exists for an engine fire to be uncontrollable. Perform the following engine fire handle checks (unless checked by the flightcrew in a manner approved by the principal operations inspector): 1. Press the left engine fire handle solenoid override button, and verify that the handle can be pulled up using normal force. CAUTION: Do not rotate the engine fire handle; inadvertent discharge of the fire extinguishing agent would result. Although not required, pulling the FIRE EXT BOTTLE – ENG L1 and L2 circuit breakers will prevent fire bottle discharge. 2. Stow the handle. 3. Press the right engine fire handle solenoid override button, and verify that the handle can be pulled up using normal force. CAUTION: Do not rotate the engine fire handle; inadvertent discharge of the fire extinguishing agent would result. Although not required, pulling the FIRE EXT BOTTLE – ENG R1 and R2 circuit breakers will prevent fire bottle discharge. 4. Stow the handle. Replace any engine fire handle that fails any operational check before further flight.

(h) Retained Restrictions on Alternative Actions and Intervals, With New Exception

This paragraph restates the requirements of paragraph (h) of AD 2019–02–03, with a new exception. Except as required by paragraph (k) of this AD: After accomplishment of the existing maintenance or inspection program revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (o) of this AD.

(i) New Required Actions

For the airplanes identified in Boeing Requirements Bulletin B787–81205–SB260008–00 RB, Issue 001, dated March 10, 2020: At the applicable times specified in the ''Compliance'' paragraph of Boeing Requirements Bulletin B787–81205–SB260008–00 RB, Issue 001, dated March 10, 2020, except as specified by paragraph (j) of this AD, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Requirements Bulletin B787–81205–SB260008–00 RB, Issue 001, dated March 10, 2020.

Note 1 to paragraph (i): Guidance for accomplishing the actions required by

paragraph (i) of this AD can be found in Boeing Service Bulletin B787–81205–SB260008–00, Issue 001, dated March 10, 2020, which is referred to in Boeing Requirements Bulletin B787–81205–SB260008–00 RB, Issue 001, dated March 10, 2020.

(j) Exception to Service Information Specifications

Where Boeing Requirements Bulletin B787–81205–SB260008–00 RB, Issue 001, dated March 10, 2020, uses the phrase ''the issue 001 date of Requirements Bulletin B787–81205–SB260008–00 RB,'' this AD requires using ''the effective date of this AD.''

(k) New Maintenance/Inspection Program Revision

Prior to or concurrently with the actions specified in paragraph (i) of this AD, or within 30 days after the effective date of the AD, whichever occurs later: Revise the existing maintenance or inspection program, as applicable, by incorporating the information specified in figure 2 to paragraph (k) of this AD into the Airworthiness Limitations Section of the Instructions for Continued Airworthiness. It is acceptable to change the limitation number from 28–AWL–FIRE to 26–AWL–FIRE, provided the rest of the information in figure 2 to paragraph (k) of this AD remains unchanged. The initial compliance time for accomplishing the actions specified in figure 2 to paragraph (k) of this AD is within 30 days after accomplishing the last 28–AWL–FIRE or 26–AWL–FIRE task, as applicable. Accomplishing the revision required by this paragraph terminates the actions required by paragraph (g) of this AD.

Figure 2 to paragraph (k): *Engine fire handle operational check*

AWL No.	Task	Interval	Applicability	Description
28-AWL -FIRE	ALI	30 days	787-8, -9, and -10 airplanes equipped with an engine fire control panel having part number 412600-001 or an engine fire shutoff switch having part number 417000-101 or 417000-102	Engine Fire Handle Operational Check. Concern: The fire handle design can result in airplanes operating with an engine fire handle that cannot be operated. A latently failed engine fire handle could prevent the fire extinguishing agent from being able to be released. In the event of certain engine fires, the potential exists for an engine fire to be uncontrollable. Perform the following engine fire handle checks (unless checked by the flightcrew in a manner approved by the principal operations inspector): 1. Press the left engine fire handle solenoid override button, and verify that the handle can be pulled up using normal force. CAUTION: Do not rotate the engine fire handle; inadvertent discharge of the fire extinguishing agent would result. Although not required, pulling the FIRE EXT BOTTLE – ENG L1 and L2 circuit breakers will prevent fire bottle discharge. 2. Stow the handle. 3. Press the right engine fire handle solenoid override button, and verify that the handle can be pulled up using normal force. CAUTION: Do not rotate the engine fire handle; inadvertent discharge of the fire extinguishing agent would result. Although not required, pulling the FIRE EXT BOTTLE – ENG R1 and R2 circuit breakers will prevent fire bottle discharge. 4. Stow the handle. Replace any engine fire handle that fails any operational check before further flight.

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(l) New Restrictions on Alternative Actions and Intervals

After accomplishment of the existing maintenance or inspection program revision required by paragraph (k) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an AMOC in accordance with the procedures specified in paragraph (o) of this AD.

(m) Terminating Action for Repetitive Inspections

Accomplishment of the actions required by paragraph (i) of this AD on all affected airplanes in an operator's fleet terminates the requirements of paragraph (k) of this AD.

(n) Parts Installation Prohibition

As of the effective date of this AD, no person may install on any airplane any engine fire control panel having part number (P/N) 412600–001, or any engine fire shutoff switch having P/N 417000–101 or P/N 417000–102.

(o) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle 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 (p)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved previously for AD 2019–02–03 are approved as AMOCs for the corresponding provisions of paragraph (g) of this AD.

(p) Related Information

(1) For more information about this AD, contact Tak Kobayashi, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3553; email: *takahisa.kobayashi@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on July 7, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–15127 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1, 38, 40, and 170

RIN 3038–AD52

Regulation Automated Trading; Withdrawal

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule; withdrawal.

SUMMARY: On December 17, 2015, the Commodity Futures Trading Commission (''CFTC'' or the ''Commission'') published a notice of proposed rulemaking, Regulation Automated Trading (''Regulation AT NPRM''). On November 25, 2016, the Commission issued a supplemental notice of proposed rulemaking to modify certain rules in the Regulation AT NPRM (''Supplemental Regulation AT NPRM''). In light of feedback the Commission received in response to the Regulation AT NPRM and Supplemental Regulation AT NPRM (together, the ''Regulation AT NPRMs''), the Commission has determined to withdraw the Regulation AT NPRMs and reject certain policy approaches relating to the regulation of automated trading contained therein.

DATES: The Commodity Futures Trading Commission is withdrawing proposed rules published on December 17, 2015 (80 FR 78824) and November 25, 2016 (81 FR 85334) as of July 15, 2020.

ADDRESSES: Comments previously submitted in response to the Regulation AT NPRMs remain on file at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581 and may also be accessed via the CFTC Comments Portal: *https://comments.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Marilee Dahlman, Special Counsel, Division of Market Oversight, *mdahlman@cftc.gov* or 202–418–5264; Joseph Otchin, Special Counsel, Division of Market Oversight, *jotchin@cftc.gov* or 202–418–5623; Esen Onur, *eonur@cftc.gov* or 202–418–6146, Office of the Chief Economist; in each case at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION: On December 17, 2015, the Commission issued the Regulation AT NPRM, which proposed pre-trade risk controls at three levels in the life-cycle of an order executed on a designated contract market (''DCM''), including: (i) Certain trading firms designated as automated traders (''AT Persons''); (ii) futures commission merchants (''FCMs''); and (iii) designated contract markets (''DCMs'').[1] In response to the Regulation AT NPRM, the Commission received 54 comment letters from exchanges, industry trade associations, public interest organizations, and others. The views expressed in the comment letters included, among other things, (i) opposition to the proposed three-level risk control framework; (ii) opposition to identification and registration of AT Persons; (iii) opposition to provisions relating to source code preservation and accessibility to the Commission without a subpoena; and (iv) opposition to prescriptive, one-sized fits all rules. On June 10, 2016, Commission staff held a public roundtable to discuss elements of the Regulation AT NRPM. In connection with the roundtable, the Commission reopened the Regulation AT NPRM comment period and received 19 additional comment letters, all of which also expressed concern with Regulation AT.

On November 25, 2016, following the conclusion of the reopened comment period, the Commission issued the Supplemental Regulation AT NPRM.[2] The Supplemental Regulation AT NPRM proposed a revised framework with pre-trade risk controls at two levels (instead of the initially proposed three levels) in the life-cycle of an order, including: (1) The AT Person *or* the FCM; and (2) the DCM. In addition, the Supplemental Regulation AT NPRM proposed some modifications to the risk control framework, trading firm registration criteria, reporting requirements, source code provisions, and compliance options for trading firms that use third-party algorithmic trading systems. The Commission received 27 comment letters during the comment period for the Supplemental Regulation AT NPRM. Commenters asserted, among other things, that (i) the proposed rules were overly prescriptive and, if the Commission was intent on proceeding with a rulemaking, should be principles-based; (ii) the proposed rules could result in redundant or overlapping risk controls; and (iii) the benefits of the proposed rules were not commensurate with the costs.

The Commission had proposed the Regulation AT NPRM and Supplemental Regulation AT NPRM based on certain assumptions about the relative risk

[1] Regulation Automated Trading, 80 FR 78824 (Dec. 17, 2015).

[2] Regulation Automated Trading, 81 FR 85334 (Nov. 25, 2016).

associated with automated trading or algorithmic trading relative to other forms of electronic trading. In addition, the Regulation AT NPRMs included provisions that would have:

(1) Required certain types of market participants, based on their trading functionality, strategies, or market access methods, to register with the Commission notwithstanding that they did not hold customer funds or otherwise intermediate futures markets.

(2) Compelled those registrants, including participants not currently registered with the Commission, to produce source code to the Commission without a subpoena; and

(3) Applied prescriptive requirements for the types of risk controls that exchanges, FCMs, and others would be required to implement.

In light of feedback the Commission received in response to the Regulation AT NPRMs, and upon further consideration, the Commission has determined to withdraw the pending Regulation AT NPRMs, to specifically reject the policy responses listed above as means of addressing the perceived risk underlying the Regulation AT NPRMs. Furthermore, the Commission has determined not to proceed with detailed, prescriptive requirements such as those contained within the Regulation AT NPRMs. Finally, the Commission has decided not to pursue regulatory proposals that would require additional classes of market participants to become registrants or compel market participants to divulge their source code and other intellectual property absent a subpoena.

Issued in Washington, DC, on June 29, 2020, by the Commission.

Christopher Kirkpatrick,

Secretary of the Commission.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Regulation Automated Trading—Commission Voting Summary, Chairman's Statement, and Commissioners' Statements

Appendix 1—Commission Voting Summary

On this matter, Chairman Tarbert and Commissioners Quintenz and Stump voted in the affirmative. Commissioners Behnam and Berkovitz voted in the negative.

Appendix 2—Supporting Statement of Chairman Heath P. Tarbert

The mission of the CFTC is to promote the integrity, resilience, and vibrancy of U.S. derivatives markets through sound regulation. We cannot achieve this mission if we rest on our laurels—particularly in relation to the ever evolving technology that makes U.S. derivatives markets the envy of the world. What is sound regulation today may not be sound regulation tomorrow.

I am reminded of the paradoxical observation of Giuseppe di Lampedusa in his prize-winning novel, The Leopard:

If we want things to stay as they are, things will have to change.[1]

While the novel focuses on the role of the aristocracy amid the social turbulence of 19th century Sicily, its central thesis—that achieving stability in changing times itself requires change—can be applied equally to the regulation of rapidly changing financial markets.

Today we are voting on a proposal to address the risk of disruptions to the electronic markets operated by futures exchanges. The risks involved are significant; disruptions to electronic trading systems can prevent market participants from executing trades and managing their risk. But how we address those risks—and the implications for the relationship between the Commission and the exchanges we regulate—is equally significant.

The Evolution of Electronic Trading

A floor trader from the 1980s and even the 1990s would scarcely recognize the typical futures exchange of the 21st Century. The screaming and shouting of buy and sell orders reminiscent of the film *Trading Places* has been replaced with silence, or perhaps the monotonous humming of large data centers. For over the past two decades, our markets have moved from open outcry trading pits to electronic platforms. Today, 96 percent of trading occurs through electronic systems, bringing with it the price discovery and hedging functions foundational to our markets.

By and large, this shift to electronic trading has benefited market participants. Spreads have narrowed,[2] liquidity has improved,[3] and transaction costs have dropped.[4] And the most unexpected benefit is that electronic markets have been able to stay open and function smoothly during the Covid–19 lockdowns. By comparison, traditional open outcry trading floors such as options pits and the floor of the New York Stock Exchange were forced to close for an extended time. Without the innovation of electronic trading, our financial markets would almost certainly have seized up and suffered even greater distress.

But like any technological innovation, electronic trading also creates new and unique risks. Today's proposal is informed by examples of disruptions in electronic markets caused by both human error as well as malfunctions in automated systems—disruptions that would not have occurred in open outcry pits. For instance, ''fat finger'' orders mistakenly entered by people, or fully automated systems inadvertently flooding matching engines with messages, are two sources of market disruptions unique to electronic markets.

Past CFTC Attempts To Address Electronic Trading Risks

The CFTC has considered the risks associated with electronic trading during much of the last decade. Seven years ago, a different set of Commissioners issued a concept release asking for public comment on what changes should be made to our regulations in light of the novel issues raised by electronic trading. Out of that concept release, the Commission later proposed Regulation AT. For all its faults, Regulation AT drove a very healthy discussion about the risks that should be addressed and the best way to do so.

Regulation AT was based on the assumption that automated trading, a subset of electronic trading, was inherently riskier than other forms of trading. As a result, Regulation AT sought to require certain automated trading firms to register with the Commission notwithstanding that they did not hold customer funds or intermediate customer orders. Most problematically, Regulation AT also would have required those firms to produce their source code to the agency upon request and without subpoena.

Regulation AT also took a prescriptive approach to the types of risk controls that exchanges, clearing members, and trading firms would be required to place on order messages. But this list was set in 2015. In effect, Regulation AT would have frozen in time a set of controls that all levels of market operators and market participants would have been required to place on trading. Since that list was proposed, financial markets have faced their highest volatility on record and futures market volumes have increased by over 50 percent.[5] Improvements in technology and computer power have been profound—Moore's Law would predict that computing power would have increased at least ten-fold in that time.[6] Of course, I commend my predecessors for focusing on the risks that electronic trading can bring. But times change, and Regulation AT would not have changed with them.

An Evolving CFTC for Evolving Markets

In withdrawing Regulation AT, the CFTC is consciously moving away from the registration requirements and source code production. But in voting to advance the Risk Principles proposal outlined further below, the CFTC is committing to address risk posed

[1] Giuseppe Tomasi di Lampedusa, *The Leopard* (Everyman's Library Ed. 1991) at p. 22.

[2] Frank, Julieta and Philip Garcia, ''Bid-Ask Spreads, Volume, and Volatility: Evidence from Livestock Markets,'' American Journal of Agricultural Economics, Vol. 93, Issue 1, page 209 (January 2011).

[3] Henderschott, Terrence, Charles M. Jones, and Albert K. Menkveld, ''Does Algorithmic Trading Improve Liquidity?'' Journal of Finance, Volume 66, Issue 1, page 1 (February 2011).

[4] Onur, Esen and Eleni Gousgounis, ''The End of an Era: Who Pays the Price when the Livestock Futures Pits Close?'', Working paper, Commodity Futures Trading Commission Office of the Chief Economist.

[5] Futures Industry Association, ''A record year for derivatives,'' (March 5, 2019), available at *https://www.fia.org/articles/record-year-derivatives.*

[6] ''Moore's Law'' predicts that the number of transistors in an integrated circuit doubles about every two years, and has held generally true since 1965. *See generally* Sneed, Annie, ''Moore's Law Keeps Going, Defying Expectations,'' Scientific American (May 19, 2015).

by electronic trading while strengthening our longstanding principles-based approach to overseeing exchanges.

The markets we regulate are changing. To maintain our regulatory functions, the CFTC must either halt that change or change our agency. Swimming against the tide of developments like electronic markets is not an option, nor should it be. The markets exist to serve the needs of market participants, not the regulator. If a technological change improves the functioning of the markets, we should embrace it. In fact, one of this agency's founding principles is that CFTC should ''foster responsible innovation.'' [7] Applying this reasoning alongside the overarching theme of *The Leopard* leads us to a single conclusion: As our markets evolve, the only real course of action is to ensure that the CFTC's regulatory framework evolves with it.

The Need for Principles-Based Regulation

So then how do we as a regulator change with the times while still fulfilling our statutory role overseeing U.S. derivatives markets? I recently published an article setting out a framework for addressing situations such as this.[8] I believe that principles-based regulations can bring simplicity and flexibility while also promoting innovation when applied in the right situations. Such an approach can also create a better supervisory model for interaction between the regulator and its regulated firms—but only so long as that oversight is not toothless.

There are a variety of circumstances in which I believe principles-based regulation would be most effective. Regulations on how exchanges manage the risks of electronic trading are a prime example. This is about risk management practices at sophisticated institutions subject to an established and ongoing supervisory relationship. But it is also an area where regulated entities have greater understanding than the regulator about the risks they face and greater knowledge about how to address those risks. As a result, exchanges need flexibility in how they manage risks as they constantly evolve.

At the same time, principles-based regulation is not ''light touch'' regulation. Without the ability to monitor compliance and enforce the rules, principles-based regulation would be toothless. Principles-based regulation of exchanges can work because the CFTC and the exchanges have constant interaction that engenders a degree of mutual trust. The CFTC—as overseen by our five-member Commission—has tools to monitor how the exchanges implement principles-based regulations through reviews of license applications and rule changes, as well as through periodic examinations and rule enforcement reviews.

Monitoring compliance alone is not enough. The regulator also needs the ability to enforce against non-compliance. Principles-based regimes ultimately give discretion to the regulated entity to find the best way to achieve a goal, so long as that method is objectively reasonable. To that end, the CFTC has a suite of tools to require changes through formal action, escalating from denial of rule change requests, to enforcement actions, to license revocations. The CFTC consistently needs to address the effectiveness and appropriateness of these levers to make sure the exchanges are meeting their regulatory objectives. And given that exchanges will be judged on a reasonableness standard, it must be the Commission itself—based on a recommendation from CFTC staff [9]—who ultimately decides whether an exchange has been objectively unreasonable in complying with our principles.

Proposed Risk Principles for Electronic Trading

This brings us to today's proposed Risk Principles. The proposal centers on a straightforward issue that I think we can all agree is important for our regulations to address. Namely, the proposal requires exchanges to take steps to prevent, detect, and mitigate market disruptions and system anomalies associated with electronic trading.

The disruptions we are concerned about can come from any number of causes, including:

Excessive messages,

fat finger orders, or

the sudden shut off of order flow from a market maker.

The key attribute of the disruptions addressed in this proposal is that they arise because of electronic trading.

To be sure, our current regulations do require exchanges to address market disruptions. But the focus of those rules has generally been on disruptions caused by sudden price swings and volatility. In effect, the proposed Risk Principles would expand the term ''market disruptions'' to cover instances where market participants' ability to access the market or manage their risks is negatively impacted by something other than price swings. This could include slowdowns or closures of gateways into the exchange's matching engine caused by excessive messages submitted by a market participant. It could also include instances when a market maker's systems shut down and the market maker stops offering quotes.

As noted in the preamble to the proposal, exchanges have worked diligently to address emerging risks associated with electronic trading. Different exchanges have put in place rules such as messaging limits and penalties when messages exceed filled trades by too large a ratio. Exchanges also may conduct due diligence on participants using certain market access methods and may require systems testing ahead of trading through those methods.

It is not surprising that exchanges have developed rules and risk controls that comport with our proposed Risk Principles. The Commission, exchanges, and market participants have a common interest in ensuring that electronic markets function properly. Moreover, this is an area where exchanges are likely to possess the best understanding of the risks presented and have control over how their own systems operate. As a result, exchanges have the incentive and the ability to address the risks arising from electronic trading. Principles-based regulations in this area will ensure that the exchanges have reasonable discretion to adjust their rules and risk controls as the situation dictates, not as the regulator dictates.

The three Risk Principles encapsulate this approach. First, exchanges must have rules to prevent, detect, and mitigate market disruptions and system anomalies associated with electronic trading. In other words, an exchange should take a macro view when assessing potential market disruptions, which can include fashioning rules applicable to all traders governing items such as onboarding, systems testing, and messaging policies. Second, exchanges must have risk controls on all electronic orders to address those same concerns. Third, exchanges must notify the CFTC of any significant market disruptions and give information on mitigation efforts.

Importantly, implementation of the Risk Principles will be subject to a reasonableness standard. The proposed Acceptable Practices clarify that an exchange would be in compliance if its rules and its risk controls are reasonably designed to meet the objectives of preventing, detecting, and mitigating market disruptions and system anomalies. The Commission will have the ability to monitor how the exchanges are complying with the Principles, and will have avenues through Commission action to sanction non-compliance.

Framework for Future Regulation

I hope that today's Risk Principles proposal will serve as a framework for future CFTC regulations. Electronic trading presents a prime example of where principles-based regulation—as opposed to prescriptive rule sets—is more likely to result in sound regulation over time. Through thoughtful analysis of the regulatory objective we aim to achieve, the nature of the market and technology we are addressing, the sophistication of the parties involved, and the nature of the CFTC's relationship with the entity being regulated, we can identify what areas are best for a prescriptive regulation or a principles-based regulation.[10] In the present context, a principles-based approach—setting forth concrete objectives while affording reasonable discretion to the exchanges—provides flexibility as electronic

[7] Commodity Exchange Act, section 3(b), 7 U.S.C. 3(b).

[8] Tarbert, Heath P., ''Rules for Principles and Principles for Rules: Tools for Crafting Sound Financial Regulation,'' Harv. Bus. L. Rev. (June 15, 2020). Vol. 10 (*https://www.hblr.org/volume-10-2019-2020/*).

[9] CFTC Staff conduct regular examinations and reviews of our registered entities, including exchanges and clearinghouses. As part of those examinations and reviews, Staff may identify issues of material non-compliance with regulations as well as recommendations to bring an entity into compliance. Ultimately, however, the Commission itself must accept an examination report or rule enforcement review report before it can become final, including any findings of non-compliance. Likewise, Staff are asked to make recommendations regarding license applications, reviews of new products and rules, and a variety of other Commission actions, although ultimate authority lies with the Commission.

[10] Tarbert, at 11–17.

trading practices evolve, while maintaining sound regulation. In sum, it recognizes that things will have to change if we want things to stay as they are.[11]

Appendix 3—Supporting Statement of Commissioner Brian Quintenz

I support today's proposal that would require designated contract markets (DCMs) to adopt rules that are reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading. It would also require DCMs to subject all electronic orders to pre-trade risk controls that are reasonably designed to prevent, detect and mitigate market disruptions and to provide prompt notice to the Commission in the event the platform experiences any significant disruptions. I believe all DCMs have already adopted regulations and pre-trade risk controls designed to address the risks posed by electronic trading. As I have noted previously, many—if not all—of the risks posed by electronic trading are already being effectively addressed through the market's incentive structure, including exchanges' and firms' own self-interest in implementing best practices. Therefore, today's proposal merely codifies the existing market practice of DCMs to have reasonable controls in place to mitigate electronic trading risks.

Significantly, the proposal puts forth a principles-based approach, allowing DCM trading and risk management controls to continue to evolve with the trading technology itself. As we have witnessed over the past decade, risk controls are constantly being updated and improved to respond to market developments. It is my view that these continuous enhancements are made possible because exchanges and firms have the flexibility and incentives to evolve and hold themselves to an ever-higher set of standards, rather than being held to a set of prescriptive regulatory requirements which can quickly become obsolete. By adopting a principles-based approach, the proposal would provide exchanges and market participants with the flexibility they need to innovate and evolve with technological developments. DCMs are well-positioned to determine and implement the rules and risk controls most effective for their markets. Under the proposed rule, DCMs would be required to adopt and implement rules and risk controls that are objectively reasonable. The Commission would monitor DCMs for compliance and take action if it determines that the DCM's rules and risk controls are objectively unreasonable.

The Technology Advisory Committee (TAC), which I am honored to sponsor, has explored the risks posed by electronic trading at length. In each of those discussions, it has become obvious that both DCMs and market participants take the risks of electronic trading seriously and have expended enormous effort and resources to address those risks.

For example, at one TAC meeting, we heard how the CME Group has implemented trading and volatility controls that complement, and in some cases exceed, eight recommendations published by the International Organization of Securities Commissions (IOSCO) regarding practices to manage volatility and preserve orderly trading. We also heard from the Futures Industry Association (FIA) about current best practices for electronic trading risk controls. FIA reported that through its surveys of exchanges, clearing firms, and trading firms, it has found widespread adoption of market integrity controls since 2010, including price banding and exchange market halts. FIA also previewed some of the next generation controls and best practices currently being developed by exchanges and firms to further refine and improve electronic trading systems. The Intercontinental Exchange (ICE) also presented on the risk controls ICE currently implements across all of its exchanges, noting how its implementation of controls was fully consistent with FIA's best practices. These presentations emphasize how critical it is for the Commission to adopt a principles-based approach that enables best practices to evolve over time. I believe the proposal issued today adopts such an approach and provides DCMs with the flexibility to continually improve their risk controls in response to technological and market advancements. I look forward to comment on the proposal.

It is also long overdue for the Commission to withdraw the Regulation Automated Trading Proposal and Supplemental Proposal (Regulation AT NPRMs). The Regulation AT NPRMs would have required certain types of market participants, based purely on their trading functionality, strategies or market access methods, to register with the Commission, notwithstanding that they did not act as intermediaries in the markets or hold customer funds. Moreover, the NPRMs proposed extremely prescriptive requirements for the types of risk controls that exchanges, futures commission merchants, and trading firms would be required to implement. Lastly, by withdrawing these NPRMs, the market and public can finally consider as dead the prior Commission's significant, and likely unconstitutional, overreach on accessing firms' proprietary source code and protected intellectual property without a subpoena.

In my view, the Regulation AT NPRMs were poorly crafted and flawed public policy that failed to understand the true risks of the electronic trading environment and the intrinsic incentives that exchanges and market participants have to mitigate and address those risks. I am pleased the Commission is officially rejecting the policy rationales and regulatory requirements proposed in the Regulation AT NPRMs and is instead embracing the principles-based approach of today's proposal.

Appendix 4—Statement of Dissent of Commissioner Rostin Behnam

I strongly support thoughtful and *meaningful* policy that addresses the use of automated systems in our markets.[1] As Chris Clearfield of System Logic, a research and consulting firm focusing on issues of risk and complexity remarked, ''In every situation, a trader or a piece of technology might fail, or a shock might trigger a liquidity event. What's important is that structures are in place to limit—not amplify—the impact on the overall system.''[2] Any rule that we put forward should both minimize the potential for market disruptions and other operational problems that may arise from the automation of order origination, transmission or execution, and create structures to absorb and buffer breakdowns when they occur. Unfortunately, today's proposal regarding Electronic Trading Risk Principles does not meaningfully achieve this, and thus I respectfully dissent.

A little over ten years ago, on May 6, 2010, the Flash Crash shook our markets.[3] The prices of many U.S.-based equity products, including stock index futures, experienced an extraordinarily rapid decline and recovery. After this event, the staffs of the U.S. Securities and Exchange Commission (''SEC'') and CFTC issued a report to the Joint CFTC–SEC Advisory Committee on Emerging Regulatory Issues.[4] The report noted that ''[o]ne key lesson is that under stressed market conditions, the automated execution of a large sell order can trigger extreme price movements, especially if the automated execution algorithm does not take prices into account. Moreover, the interaction between automated execution programs and algorithmic trading strategies can quickly erode liquidity and result in disorderly markets.''[5] In 2012, Knight Capital, a securities trading firm, suffered losses of more than $460 million due to a trading software coding error.[6] Other volatility events related to automated trading have followed with increasing regularity.[7]

After the Flash Crash, the CFTC initially worked with the SEC to establish controls to minimize the risk of automated trading disruptions. Knight Capital demonstrated that the Flash Crash was not a one-off event, and in 2013 the Commission published an extensive Concept Release on Risk Controls

[11] Di Lampedusa, at 22.

[1] The Commission's Office of the Chief Economist has found that over 96 percent of all on-exchange futures trading occurred on DCMs' electronic trading platforms. Haynes, Richard & Roberts, John S., ''Automated Trading in Futures Markets—Update #2'' at 8 (Mar. 26, 2019), available at *https://www.cftc.gov/sites/default/files/2019-04/ATS_2yr_Update_Final_2018_ada.pdf.*

[2] Chris Clearfield, *Vision Zero for Our Markets,* The Risk Desk, Dec. 21, 2016, at 4.

[3] *See* Findings Regarding the Market Events of May 6, 2010, Report of the Staffs of the CFTC and SEF to the Joint Advisory Committee on Emerging Regulatory Issues (Sept. 30, 2010), available at *http://www.cftc.gov/ucm/groups/public/@otherif/documents/ifdocs/staff-findings050610.pdf.*

[4] *Id.*

[5] *Id.* at 6.

[6] *See* SEC Press Release No. 2013–222, ''SEC Charges Knight Capital With Violations of Market Access Rule'' (Oct. 16, 2013), available at *http://www.sec.gov/News/PressRelease/Detail/PressRelease/1370539879795.*

[7] For a list of volatility events between 2014 and 2017, *see* the International Organization of Securities Commissions (''IOSCO'') March 2018 Consultant Report on Mechanisms Used by Trading Venues to Manage Extreme Volatility and Preserve Orderly Trading (''IOSCO Report''), at 3, available at *https://www.iosco.org/library/pubdocs/pdf/IOSCOPD607.pdf.*

and System Safeguards for Automated Trading Environments (''Concept Release'').[8] Following public comments on the Concept Release, the Commission published ''Regulation AT,'' which proposed a series of risk controls, transparency measures, and other safeguards to address risks arising from automated trading on designated contract markets or ''DCMs.'' [9] Reg AT proposed pre-trade risk controls at three levels in the life-cycle of an order executed on a DCM: (i) Certain trading firms; (ii) futures commission merchants (''FCMs''); and (iii) DCMs. In 2016, again based on public comments, the Commission issued a supplemental notice of proposed rulemaking for Reg AT, proposing a revised framework with controls at two levels (instead of three levels initially proposed): (1) The AT Person or the FCM; and (2) the DCM.[10]

Since 2016, the Commission has not advanced policy designed to prevent or restrain the impact of these market disruptions resulting from automated trading. While the Commission has not acted, these events have continued to occur. In September and October 2019, the Eurodollar futures market experienced a significant increase in messaging.[11] According to reports, the volume of data generated by activity in Eurodollar futures increased tenfold.[12] The DCM responded by changing its rules to increase penalties for exceeding certain messaging thresholds and cutting off connections for repeat violators.[13] The DCM acted appropriately in such a situation and strengthened the rules for its participants; however, Commission policy could well have prevented this event by requiring pre-trade risk controls, including messaging thresholds.

Given the importance of the issue, I would like to commend the Chairman for stepping forward with a proposal today. However, as I considered this proposal, I found myself questioning what the proposed Risk Principles do differently than the status quo. The preamble seems to go to great lengths to make it clear that the Commission is not asking DCMs to do anything. The preamble states that the ''Commission believes that DCMs are addressing most, if not all, of the electronic trading risks currently presented to their trading platforms.'' [14] As the preamble discusses each of the three ''new'' Risk Principles, it goes on to describe all of the actions taken by DCMs today that meet the principles. The fact that the Commission is not asking DCMs to do anything new is clearest in the cost benefit analysis, which states that ''DCMs' current risk management practices, particularly those implemented to comply with existing regulations 38.157, 38.251(c), 38.255, and 38.607, already may comply with the requirements of proposed rules 38.251(e) through 38.251(g).'' [15] If the appropriate structures are in place, and we have dutifully conducted our DCM rule enforcement reviews and have found neither deficiencies nor areas for improvement, then is the exercise before us today anything more than creating a box to check? The only potentially new aspect of this proposal is that the preamble suggests different application in the future, as circumstances change. The Commission seems to want it both ways: We want to reassure DCMs that what they do now is enough, but at the same time the new risk principles potentially provide a blank check for the Commission to apply them differently in the future. Or perhaps, viewed differently, when there is a technology failure—and there will be—will the Commission stand by its principles or will it fashion an enforcement action around a black swan event so that everyone walks away bruised, but not harmed?

For market participants, this may be extremely confusing. What precisely are DCMs being asked to do, and what will they be asked to do in the future? Frankly, I am not sure. But it could be more than they bargained for.

The first Risk Principle requires DCMs to ''[a]dopt and implement rules . . . to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading.'' None of the key terms in this principle are defined in the regulation or the preamble. DCMs are left some clues, but they are not told precisely what a market disruption or system anomaly is. Perhaps most importantly, they are not told what it means for something to be ''reasonably designed'' to prevent these things. This lack of clarity continues through the other two new Risk Principles. And while the Commission provides some clues by stating that current practice ''may'' meet the new principles, it then goes on to say that future circumstances may require future action by DCMs in order to comply with the principles.

As a recent article by our Chairman in the Harvard Business Law Review points out, the CFTC has a long tradition of principles-based regulation.[16] The concept runs through our core principles, which form the framework for much of what we do and how we regulate. It certainly is tempting to promulgate broad rules that provide the CFTC with flexibility to react to changes in the marketplace. The problem is that this flexibility comes at a number of costs—it potentially denies market participants the certainty they need to make business decisions, and, if the principles are too flexible, it denies market participants the notice and opportunity to comment that is required by the Administrative Procedures Act. These costs become too high where, as today, we promulgate rules that are too broad in their terms and too vague in application. There is a reason why the core principles for swap execution facilities (''SEFs, DCMs, and derivatives clearing organizations (''DCOs'') in our rule set are extensive, and why the regulations include appendices explaining Commission interpretation and acceptable practices. Without sufficient clarity, principles actually can become a vehicle for government overreach—a blank check for broad government action—and that includes enforcement action.

There is a saying in basketball that a good zone defense looks a lot like a man-to-man defense, and a good man-to-man defense looks a lot like a zone defense. I think the same can be said of principles-based regulation and rules-based regulation. Good principles-based regulation should look a lot like rules-based regulation—it should have enough clarity to provide market participants with certainty and the opportunity to provide comment regarding what regulation will look like.

It is worth noting that the Commission described the unanimously approved Reg AT proposal as principles-based.[17] Multiple commenters to that proposal noted that it was too principles-based.[18] I suspect that each of us on the Commission believes that the CFTC has a tradition of principles-based regulation, and that that tradition should continue. However, I think there is disagreement as to precisely what that means.[19]

Finally, I want to make a few comments on the vote regarding the withdrawal of Reg AT. On one hand, the Risk Principles proposal today expressly is not about automated or algorithmic trading. This applies to electronic trading generally. Yet there seems to be a perception that this is a replacement for Reg AT, and that is already reflected in media accounts of our action today.[20] And if

[8] Concept Release on Risk Controls and System Safeguards for Automated Trading Environments, 78 FR 56542 (Sept. 12, 2013).

[9] Regulation Automated Trading, Proposed Rule, 80 FR 78824 (Dec. 17, 2015).

[10] Supplemental Regulation AT NPRM, 81 FR 85334 (Nov. 25, 2016).

[11] *See* Osipovich, Alexander, ''Futures Exchange Reins in Runaway Trading Algorithms,'' *Wall Street Journal* (Oct. 29, 2019), available at *https://www.wsj.com/articles/futures-exchange-reins-in-runaway-trading-algorithms-11572377375.*

[12] *Id.*

[13] *See* CME Group Globex Messaging Efficiency Program, available at *https://www.cmegroup.com/globex/trade-on-cme-globex/messaging-efficiency-program.html.*

[14] Proposal at I.A.

[15] Proposal at IV.C.3.

[16] Press Release Number 8183–20, CFTC, ICYMI: Harvard Business Law Review Publishes Chairman Tarbert's Framework for Sound Regulation (June 15, 2020), *https://www.cftc.gov/PressRoom/PressReleases/8183-20.*

[17] Reg AT at 78838.

[18] *See* Comments of Americans For Financial Reform and Better Markets, Inc., available at *https://comments.cftc.gov/PublicComments/CommentList.aspx?id=1762.*

[19] As I have stated before, ''A principles-based approach provides greater flexibility, but more importantly focuses on thoughtful consideration, evaluation, and adoption of policies, procedures, and practices as opposed to checking the box on a predetermined, one-size-fits-all outcome. However, the best principles-based rules in the world will not succeed absent: (1) clear guidance from regulators; (2) adequate means to measure and ensure compliance; and (3) willingness to enforce compliance and punish those who fail to ensure compliance with the rules.'' *See* Rostin Behnam, Commissioner, CFTC, Remarks of Commissioner Rostin Behnam before the FIA/SIFMA Asset Management Group, Asset Management Derivatives Forum 2018, Dana Point, California (Feb. 8, 2018), *https://www.cftc.gov/PressRoom/SpeechesTestimony/opabehnam2.*

[20] *See* Bain, Ben, ''Flash Boys New Rules Won't Make Them Hand Over Trading Secrets,'' Bloomberg (Jun. 18, 2020), *https://www.bloomberg.com/news/articles/2020-06-18/flash-boys-new-rules-won-t-make-them-hand-over-trading-secrets.*

there is any question, the Commission is separately voting on withdrawal of Reg AT (and mentions Reg AT repeatedly in the document) at the same time it is issuing this NPRM.

A separate vote specifically to withdraw a prior Commission proposal is highly unusual—particularly in a situation where, as here, the original proposal was unanimously issued. I believe that this action establishes a dangerous precedent for a Commission that has historically prided itself on its collegiality and efforts to work in a bipartisan fashion. I have followed in a tradition of some of my predecessors on the Commission, at times voting for proposals that I would not have supported as final rules, for the purpose of advancing the conversation.[21] I worry that the withdrawal of Reg AT could lead to future withdrawals of Commission proposals, and a loss of this historical collegiality. We should be standing on the shoulders of those who came before us, not tearing down what came before us.

Market participants expressed valid concerns to the original Reg AT, as they do with many of our proposals. But, market displeasure with just one or even a few of those original policy concepts is not a reason to throw away the rest of the proposal. Let's revisit, review, and refresh sound policy to better reflect modern market structure and a healthy relationship between market participant and market regulator. I firmly believe we collectively strive for the same goal: Safe, transparent, orderly, and fair markets. Unfortunately, today's proposal does not advance the conversation, and as such I cannot support it.

The preamble to today's NPRM expressly says ''The Risk Principles proposed here are intended to accomplish a similar goal . . .'' to the original Reg AT.[22] The Reg AT proposal rule text took up more than 6 pages in the **Federal Register**, and made revisions and additions to Parts 1, 39, 40, and 170, providing a comprehensive—and principles-based—framework for addressing a very real issue that all market participants should be concerned about. Today's proposed principles are all of three sentences long. This is not a miracle of brevity. It just shows that the proposal today does not really do anything—while paradoxically writing the Commission a blank check to change its mind about what the principles mean in the future and who will stand by them when the next black swan lands.

Appendix 5—Statement of Commissioner Dan M. Berkovitz

I support issuing for public comment the proposed rule on Electronic Trading Risk Principles (''Proposed Rule''). The Proposed Rule is a limited step to address potential market disruptions arising from system errors or malfunctions in electronic trading. Although it leaves important issues unaddressed, the Proposed Rule recognizes the need to update the Commission's regulations to keep pace with the speed, interconnection, and automation of modern markets. I support the Commission's long-overdue re-engagement in this area.

While I support issuing the Proposed Rule for public comment, I do not support withdrawing the proposed rule known as Regulation Automated Trading (''Reg AT'').[1] The notice of withdrawal reflects a belief that there is nothing of value in Reg AT. That is simply not true. Reg AT was a comprehensive approach for addressing automated trading in Commission regulated markets. Certain elements of Reg AT attracted intense opposition and may have been a bridge too far. However, I applaud that proposal's efforts to identify the sources of risk and implement meaningful risk controls. I believe the comments received on Reg AT are worth evaluating going forward.

The Proposed Rule would codify in part 38 of the Commission's regulations three ''Risk Principles'' applicable to electronic trading on designated contract markets (''DCMs''). Risk Principle 1, for example, would require DCMs to implement rules applicable to market participants to prevent, detect, and mitigate market disruptions and system anomalies. Risk Principle 2 would also require DCMs to implement their own pre-trade risk controls. While worthwhile as statements of principle, these proposed requirements are drafted in terms that may ultimately prove too high-level to achieve the goal of effectively preventing, detecting, and mitigating market disruptions and system anomalies. This concern is discussed in greater detail below, and I look forward to public comment on the issue.

The Proposed Rule includes Acceptable Practices in Appendix B to part 38, which provide that a DCM can comply with the Risk Principles through rules and risk controls that are ''reasonably designed'' to prevent, detect, and mitigate market disruptions and system anomalies. The Proposed Rule specifies that reasonableness is an objective measure, and that a DCM rule or risk control that is not ''reasonably designed'' would not satisfy the Acceptable Practices or the Risk Principles. As the Proposed Rule indicates, the Commission will monitor DCMs' compliance with the Risk Principles. In this regard, the Commission has multiple oversight activities at its disposal, including market surveillance activities, reviews of new rule certifications and approval requests, and rule enforcement reviews.

The Proposed Rule is also clear on the fundamental division of authority under the Commodity Exchange Act (''CEA'') between DCMs and the Commission. Amendments to the CEA made through the Commodity Futures Modernization Act (''CFMA'') in the year 2000 introduced the core principle regime and provided DCMs with flexibility in establishing how they comply with a core principle.[2] Ten years later, however, learning from the 2008 financial crisis and the excesses of deregulation, the Dodd-Frank Act overhauled the CEA, including in its treatment of the core principle regime.[3] Specifically, section 735 of the Dodd-Frank Act made clear that a DCM's discretion with respect to core principle compliance was circumscribed by any rule or regulation that the Commission might adopt pursuant to a core principle.[4] I am able to support today's Proposed Rule for publication in the **Federal Register** because of improvements that clarify the respective authorities between a DCM and the Commission. Under the CEA, the Commission is the ultimate arbiter of whether a DCM's rules and risk controls are reasonably designed, under an objective standard. I thank the Chairman for his efforts at building consensus in this regard.

The Proposed Rule overlaps with existing requirements in part 38 of the Commission regulations, including regulation 38.255, which requires DCMs to ''establish and maintain risk control mechanisms to prevent and reduce the potential risk of price distortions and market disruptions . . . .'' [5] While the Proposed Rule and Risk Principle 2 are more explicit with respect to electronic trading, they may add little to existing requirements and practices regarding the risk controls that DCMs build into their own systems. Indeed, the Proposed Rule provides numerous examples of specific risk controls at major DCMs that likely already meet this requirement, and of disciplinary actions taken by DCMs against market participants related to electronic trading. Although the Commission articulates a need for updating its risk control requirements, the fact that the Risk Principles as proposed are likely to have no practical effect undermines the usefulness of this exercise.

The Proposed Rule possibly may be of greater benefit in with respect to Risk Principle 1 and its requirement that DCMs implement risk control rules applicable to their market participants. Market participants, who originate orders via systems ranging from comparatively simple automated order routers to nearly autonomous algorithmic trading systems, are crucial focal points for any adequate system of risk controls. An effective system of risk controls must therefore include controls at multiple stages in the life cycle of an automated order submitted to an electronic trade matching engine. Although Risk Principle 1 could benefit from greater rigor, it is nonetheless a critical recognition that market participants have an important role in any effective risk control framework.

I look forward to public comments on additional measures that the Commission should consider for effective risk controls across the ecosystem of electronic and algorithmic trading. My support for any final rule that may arise from this proposal is conditioned upon a thorough articulation of the technology-driven risks present in today's markets, and a concomitant regulatory

[21] *See* Concurring Statement of Commissioner Rostin Behnam Regarding Swap Execution Facilities and Trade Execution Requirement, (Nov. 5, 2018). *https://www.cftc.gov/PressRoom/SpeechesTestimony/behnamstatement110518a.*

[22] Proposal at I.B.

[1] Regulation Automated Trading, 80 FR 78824 (Dec. 17, 2015); 81 FR 85334 (Nov. 25, 2016) (supplemental notice of proposed rulemaking for Regulation Automated Trading).

[2] Commodity Futures Modernization Act of 2000, Public Law 106–554, 114 Stat. 2763A–365 (2000).

[3] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[4] Commodity Exchange Act section 5(d)(1)(B), 7 U.S.C. 7(d)(1)(B) (2010).

[5] 17 CFR 38.255 (2012).

response that will meaningfully address such risks. In a market environment where the vast majority of trading is now electronic and automated, inaction is a luxury that we can ill-afford.

Although the Proposed Rule may be characterized as a ''principles-based'' approach, in fact the Risk Principles are not a new approach to the regulation of risks from electronic trading. The current regulation establishing requirements on DCMs to impose risk controls—Regulation 38.255—is principles-based. Regulation 38.255 states: ''The designated contract market must establish and maintain risk control mechanisms to prevent and reduce the potential risk of price distortions and market disruptions, including, but not limited to, market restrictions that pause or halt trading in market conditions prescribed by the designated contract market.'' One might ask, therefore, why do we need another principles-based regulation when we already have a principles-based regulation? The preamble to the Proposed Rule notes the ''overlap'' between Regulation 38.255 and the proposed Risk Principles, and states ''it is beneficial to provide further clarity to DCMs about their obligations to address certain situations associated with electronic trading.'' In other words, the principles-based regulations previously adopted by the Commission *are not prescriptive enough* to address the risks currently posed by electronic trading. I fully agree. Although I am voting today to put out this proposal for public comment, I am not yet convinced—and I look forward to public comment on whether—the principles-based regulations proposed today are in fact sufficiently detailed or comprehensive to effectively address those risks.

I thank the staff of the Division of Market Oversight for their work on the Proposed Rule and for their patience as the Commission worked through multiple iterations of this proposal. I also thank the Chairman for his engagement and effort to build consensus. I believe that the Proposed Rule is a much better regulatory outcome because of the extensive dialogue and give-and-take that led to the rule before us today.

[FR Doc. 2020–14383 Filed 7–14–20; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 38

RIN 3038–AF04

Electronic Trading Risk Principles

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is proposing amendments to its regulations to address the potential risk of a designated contract market's (''DCM'') trading platform experiencing a disruption or system anomaly due to electronic trading. The proposed regulations consist of three principles applicable to DCMs concerning: The implementation of exchange rules applicable to market participants to prevent, detect, and mitigate market disruptions and system anomalies associated with electronic trading; the implementation of exchange-based pre-trade risk controls for all electronic orders; and the prompt notification of the Commission by DCMs of any significant disruptions to their electronic trading platforms. The proposed regulations are accompanied by proposed acceptable practices (''Acceptable Practices''), which provide that a DCM can comply with these principles by adopting and implementing rules and risk controls that are reasonably designed to prevent, detect, and mitigate market disruptions and system anomalies associated with electronic trading.

DATES: Comments must be received on or before August 24, 2020.

ADDRESSES: You may submit comments, identified by RIN 3038–AF04, by any of the following methods:

- *CFTC Comments Portal: https://comments.cftc.gov.* Select the ''Submit Comments'' link for this rulemaking and follow the instructions on the Public Comment Form.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Follow the same instructions as for Mail, above.

Please submit your comments using only one of these methods. Submissions through the CFTC Comments Portal are encouraged.

All comments must be submitted in English or, if not, accompanied by an English translation. Comments will be posted as received to *https://comments.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act (''FOIA''), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in 17 CFR 145.9.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse, or remove any or all of your submission from *https://comments.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under FOIA.

FOR FURTHER INFORMATION CONTACT: Marilee Dahlman, Special Counsel, *mdahlman@cftc.gov* or 202–418–5264; Joseph Otchin, Special Counsel, *jotchin@cftc.gov* or 202–418–5623, Division of Market Oversight; Esen Onur,*eonur@cftc.gov* or 202–418–6146, Office of the Chief Economist; in each case at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

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I. Introduction

A. Purpose of Electronic Trading Risk Principles

The Commission is proposing a set of principles for DCMs to address the prevention, detection, and mitigation of market disruptions and system anomalies associated with the entry of electronic orders and messages into DCMs' electronic trading platforms (''Risk Principles''). Such disruptions or anomalies may negatively impact the proper functioning of the trading platforms and/or the ability of other market participants to trade and manage their own risk. These disruptions and anomalies can arise from, among other things, excessive messaging caused by malfunctioning systems, ''fat finger'' orders or erroneous messages manually entered that result in unintentionally large or off-price orders, and loss of connection between an order management system and the trading platform.

The Commission, DCMs, and market participants have an interest in the effective prevention, detection, and mitigation of market disruptions and system anomalies associated with electronic trading activities. The Commission believes that DCMs are addressing most, if not all, of the electronic trading risks currently presented to their trading platforms. DCMs have developed pre-trade risk controls, including messaging throttles, order size maximums, and ''heartbeat'' messages confirming connectivity, to address an array of risks posed by electronic trading. DCMs also conduct due diligence and testing requirements before participants can utilize certain connectivity methods that could present risks for market disruptions and system anomalies. DCMs have developed many of these risk mitigation measures in response to real-world events, including actual or potential disruptions to their markets, as well as in response to existing rules, such as those promulgated pursuant to DCM Core Principle 4 and codified in part 38 of the Commission's regulations.

As discussed more fully below in Sections I.B and II.C, in some areas, these proposed Risk Principles are covered by existing Commission regulations, including regulations related to the prevention of market disruptions and financial risk controls. The Commission believes that because DCMs have developed robust and effective processes for identifying and managing risks, both because of their incentives to maintain markets with integrity as well as for purposes of compliance with existing Commission regulations, the Risk Principles may not necessitate the adoption of additional measures by DCMs. The Commission further believes that the proposed Risk Principles will help ensure that DCMs continue to monitor these risks as they evolve along with the markets, and make reasonable modifications as appropriate. The Commission emphasizes that the proposed Risk Principles reflect a flexible framework under which DCMs can adapt to evolving technology and markets.

B. Basic Structure of Electronic Trading Risk Principles

The Commission proposes the Risk Principles to set forth its expectation that DCMs will adopt rules and implement adequate risk controls designed to address the potential threat of market disruptions and system anomalies associated with electronic trading. In recent years, electronic trading has become increasingly prevalent on DCM markets. The Commission's Office of the Chief Economist (''OCE'') has found that over 96 percent of all on-exchange futures trading occurred on DCMs' electronic trading platforms.[1] Of the trading on electronic trading platforms, the CFTC's Market Intelligence Branch (''MIB'') in the Division of Market Oversight (''DMO'') found a consistent increase in the percentage of trading that was identified as ''automated'' relative to ''manual.'' [2]

At the same time, DCM electronic trading platforms have been faced with actual and potential disruptions unintentionally caused by market participants electronically accessing those systems. Such instances highlight the risks that DCMs face from the interaction of their own systems with those of market participants. As discussed below, DCMs have implemented a variety of controls and procedures to mitigate the market disruptions and system anomalies associated with market participants' electronic trading.

The Risk Principles supplement existing Commission regulations governing DCMs by directly addressing certain requirements in DCM Core Principle 4 and its implementing regulations, namely Commission regulations 38.251 and 38.255.[3] First, the Risk Principles provide for prospective action by DCMs to take steps to prevent market disruptions and systems anomalies, building on the Commission regulation 38.251 requirements to conduct real-time monitoring and resolve conditions that are disruptive to the market. Second, the Risk Principles explicitly focus on disruptions or system anomalies associated with electronic trading. Existing Commission regulations focus on market disruptions more generally, including for example those caused by sudden price movements.

The Risk Principles overlap to some extent with Commission regulation 38.255, which requires that DCMs establish and maintain risk control mechanisms to prevent and reduce the potential risk of price distortions and market disruptions, including, but not limited to, market restrictions that pause or halt trading in market conditions prescribed by the DCM. Although Commission regulation 38.255 and the risk controls described in Appendix B's additional guidance on Core Principle 4 discuss in part market disruptions associated with sudden price movements, the Commission believes that the risk controls required by that regulation could also extend more broadly to risks associated with electronic trading. Nevertheless, in light of the evolution of electronic trading, the Commission believes it is beneficial to provide further clarity to DCMs about their obligations to address certain situations associated with electronic trading. To that end, these Risk Principles address market disruptions and system anomalies associated with electronic trading.

As discussed in Section III below, such market disruptions or system anomalies can be the result of excessive messaging or the loss of connection between an order management system and the trading platform. Such events could impact the systems accepting messages or matching trades at the DCM. These events could have significant and negative impacts on market participants and the integrity of the market as a whole. The Commission believes that specifically identifying the need to address market disruptions or system anomalies will improve market resiliency and price discovery.

The Commission believes that a DCM's continued implementation of risk controls is important to ensure the

[1] Haynes, Richard & Roberts, John S., ''Automated Trading in Futures Markets—Update #2'' at 8 (Mar. 26, 2019), available at *https://www.cftc.gov/sites/default/files/2019-04/ATS_2yr_Update_Final_2018_ada.pdf.*

[2] Staff of the MIB, ''Impact of Automated Orders in Futures Markets'' (Mar. 2019), available at *https://www.cftc.gov/MarketReports/StaffReports/index.htm.* MIB also reported that there was no correlation between the increase in automated trading activity in these markets and any increase in volatility. Regardless, the issues addressed by the Risk Principles go beyond the discernable price movements of markets and into the underlying functionality.

[3] *See generally* 17 CFR 38.251, 38.255.

integrity of Commission-regulated markets and to foster market participants' confidence in the transactions executed on DCM platforms. This proposal is based largely on existing DCM and industry practices, including industry guidance and best practices followed by regulated entities and market participants. It also draws from comments provided to the Commission in response to proposed Regulation Automated Trading (''Regulation AT''), which includes proposed rulemakings issued in 2015 [4] and 2016 [5] described more fully below. The Risk Principles attempt to balance the need for flexibility in a rapidly-changing technological landscape with the need for an unambiguous regulatory requirement that DCMs establish rules governing electronic orders, as well as on market participants themselves, to prevent and mitigate market disruptions and system anomalies associated with electronic trading activities.

The Commission emphasizes that the Risk Principles would not create any form of strict liability for the exchanges in the event that such disruptions or anomalies occur notwithstanding such rules or controls. Nor would the Risk Principles require any specifically defined set of rules or risk controls. As provided in the proposed Acceptable Practices for implementing the Risk Principles, DCMs shall have satisfied their requirements under the Risk Principles if they have established and implemented rules and pre-trade risk controls that are reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading. The Commission interprets ''reasonably designed'' to mean that a DCM's rules and risk controls are objectively reasonable. DCM rules and pre-trade risk controls that are not ''reasonably designed'' would not satisfy the Acceptable Practices and therefore may be subject to Commission action. The Commission will monitor DCMs to ensure compliance with the Risk Principles.

As explained below, by separate action, the Commission is voting on whether to withdraw the proposed rule know as Regulation AT. Regulation AT includes, among other provisions, requirements for DCMs to implement pre-trade risk controls. The Risk Principles proposed here are intended to accomplish a similar goal as that aspect of Regulation AT, albeit through a more principles-based approach. The Risk Principles in this NPRM apply only to DCMs.[6]

II. Regulatory Approaches To Addressing Market Disruptions and System Anomalies Associated With Electronic Trading Activities

A. Examples of DCM Responses to Disruptions and Anomalies Associated With Electronic Trading Activities

As explained more fully in Section III below, the Commission's proposal seeks, in part, to explicitly recognize existing DCM processes that have evolved to minimize the frequency or severity of market disruptions or system anomalies caused by malfunctioning automated trading systems. Many DCMs have implemented exchange rules and controls to prevent, detect, and mitigate these disruptions and anomalies.[7]

DCMs have actively policed electronic trading activities that may be detrimental to the DCM. For example, they have addressed excessive messaging into their trading platforms through monitoring of compliance with DCM-established messaging thresholds and increased penalties for violations of those thresholds.

In 2011, CME Group, Inc. (''CME Group'') [8] fined a high-frequency firm for computer malfunctions, including one that prompted selling of e-mini Nasdaq 100 Index futures on CME, and another that caused a sudden increase in oil prices on NYMEX.[9] In 2014, CME Group fined several proprietary trading firms for violations related to problems with automated trading systems. In one instance, a firm sent more than 27,000 messages in less than two seconds, resulting in the exchange initiating a port closure [10] and a failure of a Globex gateway.[11]

More recently, in September and October 2019, CME Group experienced a significant increase in messaging in the Eurodollar futures market.[12] According to reports, the volume of data generated by activity in Eurodollar futures increased tenfold.[13] CME Group responded, in part, by changing its rules to increase penalties for exceeding certain messaging thresholds and cutting off connections for repeat violators.[14]

Finally, in March 2020, NYMEX fined a member for incidents in which the member, for one minute, sent a large volume of non-actionable messages resulting in latencies of over one second to other market participants.[15] Later, the same member sent another large volume of non-actionable messages, causing latencies of over one second to a larger group of market participants.[16] The first disruption was caused by a malfunction in the member's software responsible for disconnecting after a certain volume of order cancellations.[17] The second disruption was triggered when the system was taken out of production.[18] Accordingly, NYMEX found that the member had violated exchange rules prohibiting acts detrimental to the exchange and requiring diligent supervision of employees and agents.[19]

[4] Regulation Automated Trading, 80 FR 78824 (Dec. 17, 2015).

[5] Regulation Automated Trading, 81 FR 85334 (Nov. 25, 2016).

[6] The Commission will continue to monitor whether Risk Principles of this nature may be appropriate for other markets such as swap execution facilities or foreign boards of trade.

[7] These measures are discussed more fully in Section III.B and III.C. They include, for example, DCM order cancellation systems, system testing requirements on participants, and messaging controls.

[8] CME Group collectively refers to the Chicago Mercantile Exchange (''CME''), the Board of Trade of the City of Chicago, Inc. (''CBOT''), the New York Mercantile Exchange, Inc. (''NYMEX''), and the Commodity Exchange, Inc.

[9] Spicer, Jonathan, ''High-frequency firm fined for trading malfunctions,'' *Reuters* (Nov. 25, 2011), available at *https://www.reuters.com/article/us-cme-infinium-fine/high-frequency-firm-fined-for-trading-malfunctions-idUSTRE7AO1Q820111125.*

[10] CME Group may close the port for a trading session if it detects trading behavior that is potentially detrimental to its markets. Information relating to its port closure policy is available at *https://www.cmegroup.com/globex/develop-to-cme-globex/portclosure-faq.html.*

[11] Polansek, Tom, ''CME Group fines three firms for automated trading violations,'' *Reuters* (Dec. 19, 2014), available at *https://www.reuters.com/article/cme-violations-automated/cme-group-fines-three-firms-for-automated-trading-violations-idUSL1N0U31HF20141219.*

[12] *See* Osipovich, Alexander, ''Futures Exchange Reins in Runaway Trading Algorithms,'' *Wall Street Journal* (Oct. 29, 2019), available at *https://www.wsj.com/articles/futures-exchange-reins-in-runaway-trading-algorithms-11572377375.*

[13] *Id.*

[14] *See* CME Group Globex Messaging Efficiency Program, available at *https://www.cmegroup.com/globex/trade-on-cme-globex/messaging-efficiency-program.html.*

[15] *See* Notice of Disciplinary Action, NYMEX Case No. 18–0989–BC (Mar. 16, 2020), available at *https://www.cmegroup.com/tools-information/advisorySearch.html#cat=advisorynotices%3AAdvisory+Notices%2FMarket+Regulation+Advisories&pageNumber=1&subcat=advisory notices%3AAdvisory+Notices%2FMarket+Regulation+Advisories%2FBusiness-Conduct-Committee&searchLocations=%2Fcontent%2Fcmegroup%2F.*

[16] *See id.*

[17] *See id.*

[18] *See id.*

[19] *See id.*

B. NFA Efforts To Prevent Market Disruptions and System Anomalies

In June 2002, the National Futures Association (''NFA'') issued Interpretive Notice 9046 (''Interpretative Notice''), subsequently revised in December 2006, relating to the supervision of automated order routing systems (''AORSs'').[20] The Interpretative Notice applies to all NFA members that employ AORSs, and provides binding guidance to, among other things, implement firewalls, conduct testing, and perform capacity reviews, as well as consider implementation of pre-trade controls. In light of the changes to electronic trading since 2006, the Commission encourages NFA to evaluate whether additional supervisory guidance should be provided to its members.

C. CFTC Regulations Governing DCM Operations and Risk Controls

Several existing CFTC regulations in part 38 generally govern the DCM's role in monitoring for, and mitigating the effects of, market disruptions and system anomalies.

For example, under DCM Core Principle 2, Commission regulation 38.157 requires a DCM to conduct real-time market monitoring of all trading activity on its electronic trading platform(s) to identify disorderly trading and any market or system anomalies.[21] Regulations under Core Principle 4 provide additional requirements for DCMs. Specifically, Commission regulation 38.251(c) requires each DCM to demonstrate an effective program for conducting real-time monitoring of market conditions, price movements, and volumes, in order to detect abnormalities and, when necessary, to make a good-faith effort to resolve conditions that are, or threaten to be, disruptive to the market. However, these requirements address real-time monitoring and after-the-fact accountability, as opposed to the anticipatory nature of the Risk Principles.

In addition, Commission regulation 38.255 requires DCMs to establish and maintain risk control mechanisms to prevent and reduce the potential risk of price distortions and market disruptions, including, but not limited to, market restrictions that pause or halt trading in market conditions prescribed by the DCM.[22]

The Commission also has adopted risk control requirements for exchanges that provide direct electronic access to market participants. Commission regulation 38.607 requires DCMs that permit direct electronic access to have effective systems and controls reasonably designed to facilitate a futures commission merchant's (''FCM's'') management of financial risk.[23] In addition, existing part 38 regulations on DCM system safeguards promulgated under DCM Core Principle 20 (in particular, Commission regulations 38.1050 and 38.1051) focus on whether DCMs' internal systems are operating correctly.[24]

D. Prior Commission Proposals and Requests for Comments on Electronic Trading

In 2013, the Commission published an extensive Concept Release on Risk Controls and System Safeguards for Automated Trading Environments (''Concept Release''), which was open for public comment.[25] On December 17, 2015, the Commission published a notice of proposed rulemaking (''Regulation AT NPRM'') that proposed a series of risk controls, registration and recordkeeping requirements, transparency measures, and other safeguards to address risks arising from automated trading on DCMs.[26] On November 25, 2016, the Commission issued a supplemental notice of proposed rulemaking for Regulation AT (''Supplemental Regulation AT NPRM'').[27] The Supplemental Regulation AT NPRM proposed to modify certain proposals in the Regulation AT NPRM, including the risk control framework.

E. Market Participants' Discussions of Best Practices

At an October 5, 2018 Technology Advisory Committee (''TAC'') [28] meeting, a member of the TAC's Subcommittee on Automated and Modern Trading Markets (''Modern Trading Subcommittee''), CME Group, discussed the March 2018 International Organization of Securities Commissions (''IOSCO'') Consultation Report, ''Mechanisms Used by Trading Venues to Manage Extreme Volatility and Preserve Orderly Trading.'' [29] In that report, IOSCO recommended that DCMs: (1) Have appropriate volatility control mechanisms; (2) ensure that volatility control mechanisms are appropriately calibrated; (3) regularly monitor volatility control mechanisms; (4) provide upon request of regulatory authorities information regarding the triggering of volatility control mechanisms; (5) communicate information to market participants and the public about volatility control mechanisms; (6) make available to market participants information regarding the triggering of a volatility control mechanism; and (7) communicate with other trading venues where the same or related instruments

[20] NFA, Interpretive Notice 9046, ''Supervision of the Use of Automated Order-Routing Systems'' (Dec. 12, 2006), available at *https://www.nfa.futures.org/rulebook/rules.aspx?RuleID=9046&Section=9*.

[21] 17 CFR 38.157.

[22] 17 CFR 38.255. The Commission has provided Guidance and Acceptable Practices on these regulatory provisions.

The Core Principle 4 Guidance provides that the detection and prevention of market manipulation, disruptions, and distortions should be incorporated into the design of programs for monitoring trading activity. Monitoring of intraday trading should include the capacity to detect developing market anomalies, including abnormal price movements and unusual trading volumes, and position-limit violations. The DCM should have rules in place that allow it broad powers to intervene to prevent or reduce market disruptions. Once a threatened or actual disruption is detected, the DCM should take steps to prevent the disruption or reduce its severity. *See* Appendix B to part 38—Guidance on, and Acceptable Practices in, Compliance with Core Principles, Core Principle 4, paragraph (a).

The Core Principle 4 Acceptable Practices also provide that an acceptable program for preventing market disruptions must demonstrate appropriate trade risk controls, in addition to pauses and halts. Such controls must be adapted to the unique characteristics of the markets to which they apply and must be designed to avoid market disruptions without unduly interfering with that market's price discovery function. The DCM may choose from among controls that include: Pre-trade limits on order size, price collars or bands around the current price, message throttles, and daily price limits, or design other types of controls. Within the specific array of controls selected, the DCM also must set the parameters for those controls, as long as the types of controls and their specific parameters are reasonably likely to serve the purpose of preventing market disruptions and distortions. If a contract is linked to, or is a substitute for, other contracts, either listed on its market or on other trading venues, the DCM must, to the extent practicable, coordinate its risk controls with any similar controls placed on those other contracts. If a contract is based on the price of an equity security or the level of an equity index, such risk controls must, to the extent practicable, be coordinated with any similar controls placed on national security exchanges. *Id.* at paragraph (b)(5).

[23] 17 CFR 38.607.

[24] 17 CFR 38.1050 and 38.1051.

[25] Concept Release on Risk Controls and System Safeguards for Automated Trading Environments, 78 FR 56542 (Sept. 12, 2013).

[26] Regulation AT NPRM, *supra* note 4.

[27] Supplemental Regulation AT NPRM, *supra* note 5.

[28] The TAC was created in 1999 to advise the Commission on the impact and implications of technological innovations on financial services and the futures markets, and the appropriate legislative and regulatory response to increasing use of technology in the markets. Members include representatives of futures exchanges, self-regulatory organizations, financial intermediaries, market participants, and traders.

[29] CME Group, ''Automated and Modern Trading Markets Subcommittee'' (Oct. 5, 2018), available at: *https://www.cftc.gov/About/CFTCCommittees/TechnologyAdvisory/tac_meetings.html*.

are traded.[30] CME Group reported that it was in compliance with the IOSCO recommendations regarding volatility control mechanisms through the implementation of: (1) In line credit controls; (2) velocity logic functionality; (3) price limits and circuit breakers; (4) protection points for market and stop orders; and (5) price banding.[31]

On October 3, 2019, the TAC held a public meeting in which it heard presentations from the Modern Trading Subcommittee. During this meeting, the Futures Industry Association (''FIA'') presented to the CFTC's TAC certain best practices for exchange risk controls (''FIA TAC Presentation'').[32] FIA discussed four principles to address market disruptions from electronic trading activities: (1) All electronic orders should be subject to exchange-based pre-trade and other risk controls and policies designed to prevent inadvertent and disruptive orders and reduce excessive messaging; (2) exchanges should provide tools to control orders that may no longer be under the control of the trading system; (3) exchanges should adopt policies to require operators of electronic trading systems to ensure that their systems are tested before accessing the exchange; and (4) exchanges should be able to identify the originator of an electronic order and whether the order was generated automatically or manually.[33]

FIA also reported that its multiple surveys of exchanges, clearing firms and traders over the last ten years demonstrate that there has been a substantial increase in the implementation of market integrity controls since 2010, including price banding and exchange market halts.[34] They found that there has been a steady upward trend in the adoption of basic pre-trade controls, such as order size and net position limits, and that controls and tools such as self-match prevention, drop copy feeds, and kill switches are widely available.[35] According to FIA, there has been a steady upward trend in the voluntary adoption of controls across the various participants in the life cycle of the trade (traders, brokers, exchanges, and clearing firms) and generally positive feedback to industry initiatives and responsiveness to identify and self-solve industry risks.[36]

At that same October 2019 TAC meeting, the Intercontinental Exchange (''ICE'') reported on its implementation of a broad array of risk controls consistent with FIA's findings.[37] ICE's risk controls include: (1) Price banding on collars that warn and reject orders that are outside the band of current market value; (2) circuit breakers when there are large price moves in a short period of time; (3) trades outside of a certain range reviewed by ICE Operations; (4) message throttle limits to prevent malfunctioning software from overwhelming the market; and (5) auto cancellation of open orders upon session disconnect or loss of heartbeat.[38]

III. Risk Principles

A. Electronic Trading, Electronic Orders, Market Disruption, and System Anomalies

The proposed Risk Principles focus on market disruptions or system anomalies associated with electronic trading activities. While not defined in the regulation text, this preamble will broadly discuss the goals of the Risk Principles through these terms. The Commission intends, by not defining the terms in a static way, that the application of these Risk Principles by DCMs and the Commission will be able to evolve over time along with market developments. However, a general discussion of those terms in the context of today's electronic markets will provide the public and, in particular, DCMs, guidance for applying these Risk Principles.

Electronic trading encompasses a wide scope of trading, and should be understood, for purposes of this proposed rulemaking, to include all trading and order messages submitted by electronic means to the DCM's electronic trading platform. This would include both automated and manual order entry.

The Commission considers the term ''market disruption,'' for purposes of the Risk Principles, generally to include an event originating with a market participant that significantly disrupts the: (1) Operation of the DCM on which such participant is trading; or (2) the ability of other market participants to trade on the DCM on which such participant is trading. For the purposes of the Risk Principles, ''system anomalies'' are unexpected conditions that occur in a market participant's functional system which cause a similar disruption to the operation of the DCM or the ability of market participants to trade on the DCM. ''Operation of the DCM,'' for the purposes of this proposal, refers specifically to the exchange's order processing and trade execution functions.[39]

A market disruption may include a situation where the ability of other market participants to engage in price discovery or risk management on a DCM is significantly impacted by a malfunction of a DCM participant's trading system. Accordingly, a market participant's automated trading system malfunction, for instance, on its own, would not be considered disruptive unless there was some significant consequence to other market participants' ability to trade or manage risk. As noted below in the discussion of Risk Principle 3, a significant market disruption would include a situation where the ability of other market participants to execute trades, engage in price discovery, or manage their risks is materially impacted by a malfunction of a participant's trading system. Similarly, market volatility by itself is not a market disruption. For example, the fact of a market being ''limit up'' or ''limit down'' would not, on its own, be considered disruptive, regardless of the presence of automated trading functionality in that market or during that trading period.

The Commission believes that DCMs should have discretion to precisely identify market disruptions and system anomalies as they relate to the DCMs' particular markets and market participants' trading activity. The Commission also recognizes that each DCM may have different understandings of, or parameters for, disruptive behavior in its market. This may result in a certain degree of differences in DCM rules implementing the Risk Principles. The Commission does not believe that a lack of uniformity between DCMs' rules and risk controls renders a particular DCM's rules or risk controls *per se* unreasonable.

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[30] *Id.*

[31] *Id.*

[32] FIA, ''Best Practices for Exchange Risk Controls'' (Oct. 3, 2019), available at *https://www.cftc.gov/PressRoom/Events/opaeventtac100319.*

[33] *See id.* at 4. FIA has also published principles-based guidance on European governance and control requirements for firms working with third-party algorithmic trading providers. *See* FIA, ''Guidance for Firms Working with Third-Party Algorithmic Trading System Providers on European Governance and Control Requirements'' (Dec. 2018), available at *https://www.fia.org/sites/default/files/2020-02/Guidance%20for%20Firms%20and%20Third%20Party%20Algorithmic%20Trading%20Providers.pdf.*

[34] FIA, ''Best Practices for Exchange Risk Controls'' *supra* note 32, at 7.

[35] *Id.*

[36] *Id.*

[37] ICE, ''ICE Futures Exchange Risk Controls'' (Oct. 3, 2019), available at: *https://www.cftc.gov/About/CFTCCommittees/TechnologyAdvisory/tac_meetings.html.*

[38] *Id.*

[39] The Commission notes that the term ''electronic trading'' includes both cleared and uncleared trades.

Request for Comment

1. Is the Commission's description of ''electronic trading'' sufficiently clear? If not, please explain.

2. This rulemaking uses the term ''market disruption'' to describe the disruptive effects to be prevented, detected, and mitigated through these Risk Principles. Is it preferable to use the term ''trading disruption,'' ''trading operations disruption,'' or another alternative term instead? If so, which term should be used and why?

3. What type of unscheduled halts in trading would constitute ''market disruptions'' that impact the ability of other market participants to trade or manage their risk?

4. What amount of latency to other market participants (measured in milliseconds) should be considered a market disruption? How can DCMs evaluate changes over time in the amount of latency that should be considered a market disruption?

5. Are there other types of risk that may lead to market disruptions that the Commission should address or be aware of?

6. Is there guidance that the Commission can give DCMs for how best to monitor for emerging risks that are not mitigated or contemplated by existing risk controls or procedures?

7. The Commission recognizes that there are alternative approaches to the proposed Risk Principles to address the risk of market disruption resulting from electronic trading on DCMs by market participants. The Commission requests comment on whether an alternative to what is proposed would result in a more effective approach (meaning, alternative to these Risk Principles as well as the withdrawn Regulation AT), and whether such alternative offers a superior cost-benefit profile. Please provide support for any alternative approach.

8. Given that the Risk Principles overlap to some extent with Commission regulation 38.255, which specifically addresses risk controls for trading, would it be preferable to codify the three Risk Principles within existing regulation 38.255 rather than within regulation 38.251, which covers general requirements relating to the prevention of market disruption?

B. Proposed Regulation 38.251(e)—Risk Principle 1

Proposed regulation 38.251(e)—Risk Principle 1—provides that a DCM must adopt and implement rules governing market participants subject to its jurisdiction to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading.

The proposed Acceptable Practices for proposed regulation 38.251(e) provide DCMs with discretion to determine what rules to impose on market participants to address electronic trading risks, subject to Commission action. The Commission recognizes that a DCM is well-positioned to assess the market disruption and system anomaly risks posed by its markets and market participant activity, and to design appropriate measures to address those risks. The Acceptable Practices are intended to provide DCMs with reasonable discretion to impose rules to prevent, detect, and mitigate market disruption. Consistent with existing DCM practices, this could include requiring market participants to implement exchange-provided risk controls and order cancellation functionality, and requiring testing in advance of exchange access. In developing a framework to address these risks, DCMs should take into account industry best practices and what risk controls and testing practices are technologically feasible.

The Commission acknowledges that there are various DCM practices in place today that are consistent with proposed regulation 38.251(e), such as exchange-provided risk controls primarily geared to address financial risk or market risk that also address preventing or mitigating market disruptions or system anomalies caused by electronic trading activities. For example, CME Group requires its clearing member firms to utilize the Globex Credit Control system to set maximum order size limits for individual customers.[40] CME Group also provides order cancellation systems including a ''kill switch'' functionality)[41] to clearing and execution firms.[42] ICE will automatically cancel open orders upon session disconnect or loss of heartbeat.[43] DCMs also impose system testing requirements on participants.[44]

One recent example highlights measures that a DCM could adopt and implement to prevent and mitigate a potential market disruption. As discussed above in Section II.A, in the fall of 2019, CME Group experienced a significant increase in messaging in the Eurodollar futures market. CME Group already had a messaging policy in place, ''designed to support efficient market operations and foster high quality, liquid markets by encouraging responsible and reasonable messaging practices by market participants.''[45] In response to the increasing messaging activity in the Eurodollar market, CME Group changed its rules to increase penalties for exceeding certain messaging thresholds, and cut off connections for repeat violators.[46] Implementing messaging limits on its market participants, and adjusting them as appropriate in light of potentially disruptive trading behaviors, as well as disconnecting access if necessary, are measures that DCMs could consider to address proposed regulation 38.251(e).

Other DCMs have also addressed the potential for similar activity to cause market disruptions or system anomalies. CFE Rule 513(c) provides that CFE may limit the number of messages or the amount of data transmitted by Trading Privilege Holders to the CFE System in order to protect the integrity of the CFE System.[47] In addition, CFE may impose

[40] CME Group Regulation AT NPRM Letter, at 16–17.

[41] CME Group's ''kill switch'' functionality is defined as an exchange-provided graphical user interface that allows clearing firms and permissioned executing firms a one-step shutdown of CME Globex activity at the clearing firm level, Globex firm level, and/or by SenderComp IDs. When a kill switch is activated, order entry is blocked and working orders are cancelled for selected SenderComp IDs. *See* CME Group's discussion of risk management tools, available at*https://www.cmegroup.com/globex/trade-on-cme-globex/risk-management-tools.html.*

[42] *See id.*

[43] ICE Presentation to TAC, at 3 (Oct. 2019), available at *https://www.cftc.gov/PressRoom/Events/opaeventtac100319.*

[44] For example, CBOE Futures Exchange, LLC (''CFE'') Rule 513C provides that the exchange may from time to time prescribe systems testing requirements applicable to ''Trading Privilege Holders'' relating to connectivity to the CFE's system and CFE functionality. Such participants must maintain adequate documentation of tests and provide reports to the exchange as requested. CFE Rule 513C is available at *https://www.cboe.com/aboutcboe/about-cfe/legal-regulatory.*

CME Group requires that all client systems transacting on CME Globex via iLink order routing or processing CME Group market data are certified by AutoCert+, an automated testing tool for validating client system functionality, and offers customer testing environments for system validation prior to connecting to and transacting on CME Group platforms. CME Group indicates that ''Certification ensures messaging and processing reliability and the capability to gracefully recover during abnormal message processing events.'' *See* CME Group's website at *https://www.cmegroup.com/confluence/display/EPICSANDBOX/Client+Application+Testing+and+Certification.*

At CBOT, market participants have been fined for not testing their systems before using them to enter orders into the production market under CBOT Rule 432.Q, which governs acts that are considered detrimental to the interests or welfare of the exchange. *See* FIA Supplemental NPRM Letter, at 4 n.12.

[45] *See* CME Globex Messaging Efficiency Program policies, available at *https://www.cmegroup.com/globex/trade-on-cme-globex/messaging-efficiency-program.html.*

[46] Osipovich, Alexander, ''Futures Exchange Reins in Runaway Trading Algorithms,'' *supra* note 12.

[47] CFE Rules 513(c) and 513A(h), available at *https://www.cboe.com/aboutcboe/about-cfe/legal-regulatory.*

restrictions on the use of any individual access to the CFE System, including temporary termination of individual access and activation by CFE of its kill switch function under Rule 513A(j), if CFE believes such restrictions are necessary to ensure the proper performance of the CFE System or to protect the integrity of the market.[48]

In the October 2019 FIA TAC Presentation, FIA indicated that since 2010, it has conducted various surveys of exchanges, as well as a sampling of its members, including clearing firms and principal traders. These surveys reflect clearing firms' broad use (either internally or as offered by an exchange) of: (1) Message and execution throttles; (2) price collars; (3) maximum order sizes; (4) order, trade, and position drop copy; and 5) order cancellation capabilities.[49] FIA noted in its presentation that initiatives are underway at most exchanges to develop Application Programming Interface access to various risk controls, as well as to improve the functionality available in exchange certification and conformance testing environments.[50]

The Commission believes that the current industry practices described above serve as examples of measures that all DCMs could adopt, as appropriate, as rules to address the potential for electronic trading activities to cause market disruptions and system anomalies as those risks are presented today. As noted above, the Commission believes that this Risk Principle will help ensure that DCMs continue to monitor these risks as they evolve along with the markets, and make reasonable changes as appropriate to address those evolving risks.

The Commission acknowledges that it may not be possible for a DCM to prevent all market disruptions and system anomalies. A DCM would not necessarily have violated this principle if a market disruption or anomaly does occur, despite its having rules in place. To that end, the Commission is proposing Acceptable Practices in Appendix B to part 38 with respect to DCM obligations under proposed regulation 38.251(e). The proposed Acceptable Practices provide that a DCM can comply with the requirements of proposed 38.251(e) by adopting rules that are ''reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading.'' The Commission interprets ''reasonably designed'' to require that a DCM create rules that are objectively reasonable.

Request for Comment

The Commission requests comment on all aspects of proposed regulation 38.251(e). The Commission also invites specific comments on the following:

9. The Commission recognizes that DCMs may differ in what rules they establish to prevent, detect, and mitigate market disruption and system anomalies. Would such disparity have a harmful effect on market liquidity or integrity?

10. Is the proposed Acceptable Practice for regulation 38.251(e) appropriate?

11. What rules have DCMs found to be effective in preventing, detecting, or mitigating the types of market disruptions and system anomalies associated with electronic trading? Should the Commission include any particular types of rules as Acceptable Practices for compliance with proposed regulation 38.251(e)?

C. Proposed Regulation 38.251(f)—Risk Principle 2

Proposed regulation 38.251(f)—Risk Principle 2—provides that DCMs must subject all electronic orders to exchange-based pre-trade risk controls to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading.

This proposed principle obligates DCMs to implement exchange-based pre-trade risk controls on all electronic orders.[51] The Commission concurs with the broad agreement among market participants, market infrastructure operators, and intermediaries that ''[p]re-trade risk controls are the responsibility of all market participants, and when implemented properly and appropriate to the nature of the activity, have been proven to be the most effective safeguard for the markets, and should be applied comprehensively to all electronic orders.'' [52] In light of this public comment and the overall migration to electronic trading, the Commission proposes to apply Risk Principle 2 to all electronic trading.

The Commission believes that the existing DCM Core Principle 4 Acceptable Practices list appropriate DCM-implemented risk controls, including pre-trade limits on order size, price collars or bands around the current price, message throttles, and daily price limits. The existing Acceptable Practices further provide that the DCM must set the parameters for these controls, so long as the types of controls and their specific parameters are reasonably likely to serve the purpose of preventing market disruptions and price distortions.[53] Proposed regulation 38.251(f) does not change the Acceptable Practices for regulation 38.255, which remain in effect.

The Commission also notes that the October 2019 FIA TAC Presentation illustrates measures that DCMs could consider adopting to address risks posed by electronic trading. In addition to the four principles described in Section II.E above, FIA stated that, ''[a]ll users and providers of electronic trading systems have a responsibility to implement pre-trade risk controls appropriate to their role in the market, whether initiating the trade, routing the trade, executing the trade, or clearing the trade.'' [54] FIA's presentation also listed specific pre-trade risk controls that are critical in preventing market disruption, which are implemented at trader, broker, and exchange levels, which included, among others, fat finger (maximum size), market data reasonability checks, repeatable execution limits, and messaging limits and throttles.[55]

The purpose of proposed regulation 38.251(f) (Risk Principle 2) is to require DCMs to consider market participants' trading activities when designing and implementing exchange-based risk controls to address market disruptive events. While existing guidance provides that exchange-based controls ''must be adapted to the unique characteristics of the markets to which they apply and must be designed to avoid market disruptions without unduly interfering with that market's price discovery function,'' Risk

[48] *See id.*

[49] FIA, ''Best Practices for Exchange Risk Controls'' *supra* note 32, at 8. *See, e.g.,* CFE Rule 513A (describing pre-trade risk control mechanisms provided within CFE's trading system, and whether each control is to be set by the market particpant or the exchange).

[50] FIA, ''Best Practices for Exchange Risk Controls'' *supra* note 32, at 9.

[51] While the Risk Principles would apply solely to DCMs, this proposal should not be interpreted as relieving market participants of any existing obligation to implement their own risk controls under any applicable Commission or exchange rules, including Commission regulation 1.11 applicable to FCMs. Rather, consistent with industry practice, Commission regulation 1.11(e)(3)(ii) (requiring automated financial risk management controls to address operational risk), and any rules DCMs impose pursuant to proposed regulation 38.251(e) (Risk Principle 1), the Commission expects that market participants would continue to implement their own controls.

[52] FIA, FIA PTG, MFA, ISDA, and SIFMA AMG Combined Comment Letter to Regulation AT NPRM, at 3 (June 24, 2016).

[53] Appendix B to part 38—Guidance on, and Acceptable Practices in, Compliance with Core Principles, Core Principle 4 (paragraph (a)).

[54] FIA, ''Best Practices for Exchange Risk Controls'' *supra* note 32, at 5.

[55] *See id.*

Principle 2 more explicitly requires DCMs to consider risk controls that specifically address market disruptions or system anomalies associated with electronic trading activity, and implement appropriate controls. It provides flexibility for technological progress (for example, while controls called ''message throttles'' may be appropriate now, industry measures to address excessive messaging could change in the future). It also allows DMO to assess compliant risk controls as part of its rule enforcement review program, comparing all DCMs to a baseline of controls on electronic trading and electronic order entry that are prevalent and effective across DCMs.

Given the prevalence of existing exchange-based risk controls, the Commission expects that many DCM practices are consistent with proposed regulation 38.251(f). Depending on the circumstances, it may be possible for a DCM to appropriately conclude that its existing pre-trade risk controls satisfy the proposed Acceptable Practices for proposed regulation 38.251(f), and that the adoption of this rule does not require it to do something more, or different, at this time. As noted above, existing regulation 38.255 is similar to proposed regulation 38.251(f) in that it requires exchange-based risk controls to prevent and reduce the potential risk of market disruptions. However, regulation 38.255 does not explicitly address the full scope of risks addressed by proposed regulation 38.251(f). For example, the preamble to the part 38 final rules states that proposed 38.255 requires DCMs to have in place effective risk controls including, but not limited to, pauses and/or halts to trading in the event of extraordinary price movements that may result in distorted prices or trigger market disruptions.[56] Proposed regulation 38.251(f) would more explicitly address other types of market disruptions associated with electronic trading. Its requirement that DCMs implement risk controls to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading applies to any disruptive event that significantly impairs the ability of market participants to manage risk or otherwise trade. Further, proposed regulation 38.251(f), specifically applies to electronic orders. Risk Principle 2 provides clarity to DCMs that their exchange-based risk controls must address market disruptions caused by electronic trading, including those related to price movements as well as other events that impair market participants' ability to trade.

Examples of existing exchange-based risk controls include: (1) CME Group automated messaging volume controls; price banding set at individual product level and protection point controls; ''fat finger'' backstop of ''Maximum Order Size Protection'' functionality that sets a pre-defined maximum order size cap on an individual contract basis; [57] and (2) ICE message throttle limits (preventing malfunctioning software from overwhelming the market); price banding or collars that warn and reject orders outside the band of current market value; and interval price limits (facilitating orderly trading when there are large price moves in a short period of time).[58]

FIA's 2018 survey of exchange-traded derivatives venues showed that 11 out of 17 responding venues had implemented dynamic price bands and that 13 had implemented trading halts during extreme volatility.[59] Notably, every exchange in the Americas that responded to the survey had implemented both price banding and trading halts.[60]

The Commission reiterates the concept noted above that DCMs' understanding of risks posed by electronic trading, and the reasonably appropriate measures to address them, may evolve over time. Accordingly, the Commission would expect DCMs to continue to develop controls that are effective to prevent, detect, and mitigate market disruptions or system anomalies, regardless of whether they are named in existing part 38 Acceptable Practices.

As with proposed regulation 38.251(e), the Commission is proposing Acceptable Practices for proposed regulation 38.251(f) to provide that a DCM can comply with the requirements of proposed regulation 38.251(f) for risk controls by adopting rules that are ''reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading.'' This Acceptable Practice is consistent with the existing Acceptable Practice in Appendix B to part 38 corresponding to the risk controls required by existing 38.255, which provides, in part, that a DCM's risk control program can comply with its obligations ''so long as the types of controls and their specific parameters are reasonably likely to serve the purpose of preventing market disruptions and price distortions.'' [61]

Request for Comment

The Commission requests comment on all aspects of proposed regulation 38.251(f). The Commission also invites specific comments on the following:

12. The Acceptable Practices for Core Principle 2 include pre-trade limits on order size, price collars or bands around the current price, message throttles, and daily price limits. Do DCMs consider these controls to be effective in preventing market disruptions in today's markets?

13. In addition to the risk controls listed in the Acceptable Practices for Core Principle 2, what risk controls do DCMs consider to be most effective in preventing market disruptions and addressing risk as described in this proposal?

14. Are the proposed risk controls set forth in the Acceptable Practices for proposed regulation 38.251(f) appropriate?

15. Should the Commission include any particular types of risk controls as Acceptable Practices for compliance with proposed regulation 38.251(f)?

D. Proposed Regulation 38.251(g)—Risk Principle 3

Proposed regulation 38.251(g)—Risk Principle 3—provides that a DCM must promptly notify Commission staff of a significant disruption to its electronic trading platform(s) and provide timely information on the causes and remediation.

Proposed regulation 38.251(g) includes a ''significant'' threshold for

[56] Core Principles and Other Requirements for Designated Contract Markets, 77 FR 36612, 36637 (June 19, 2012).

[57] CME Group Regulation AT NPRM Letter, NPRM at 14–17 (Mar. 16, 2016).

[58] ICE TAC Presentation, *supra* note 42, at 3.

[59] Subcommittee Presentation at 5 (Oct. 5, 2018). The presentation is available at *https://www.cftc.gov/About/CFTCCommittees/TechnologyAdvisory/tac_meetings.html.*

[60] *See id.*

[61] Regarding risk controls for trading, the Acceptable Practices for Regulation 38.255 provide that an acceptable program for preventing market disruptions must demonstrate appropriate trade risk controls, in addition to pauses and halts. Such controls must be adapted to the unique characteristics of the markets to which they apply and must be designed to avoid market disruptions without unduly interfering with that market's price discovery function. The DCM may choose from among controls that include: Pre-trade limits on order size, price collars or bands around the current price, message throttles, and daily price limits, or design other types of controls. Within the specific array of controls that are selected, the DCM also must set the parameters for those controls, so long as the types of controls and their specific parameters are reasonably likely to serve the purpose of preventing market disruptions and price distortions. If a contract is linked to, or is a substitute for, other contracts, either listed on its market or on other trading venues, the DCM must, to the extent practicable, coordinate its risk controls with any similar controls placed on those other contracts. If a contract is based on the price of an equity security or the level of an equity index, such risk controls must, to the extent practicable, be coordinated with any similar controls placed on national security exchanges.

notification. An internal disruption in a market participant's own trading system should not be considered significant unless it causes a market disruption materially affecting the DCM's trading platform and other market participants. A significant disruption is a situation where the ability of other market participants to execute trades, engage in price discovery, or manage their risks is materially impacted by a malfunction of a market participant's trading system. Proposed regulation 38.251(g) would obligate the DCM to notify the Commission of this event promptly after the DCM becomes aware of it.

Proposed regulation 38.251(g) is to be distinguished from existing Commission regulation 38.1051(e), which requires DCMs to notify the Commission in the event of, among other things, significant systems malfunctions. Proposed regulation 38.251(g) addresses market disruptive events, as opposed to incidents that threaten the integrity of a DCM's internal technological systems. Thus, unlike existing Commission regulation 38.1051(e), proposed regulation 38.251(g) would address malfunctions of the technological systems of trading firms and other non-DCM market participants that cause disruptions of the DCM's trading platform.

The Commission believes that the notification requirement under proposed regulation 38.251(g) will assist the Commission's oversight and its ability to monitor and assess market disruptions across all DCMs. The Commission expects that notification pursuant to proposed regulation 38.251(g) would take a similar form to the current notification process for electronic trading halts, cyber security incidents, or activation of a DCM's business continuity-disaster recovery plan under Commission regulation 38.1051(e).

Request for Comment

The Commission requests comment on all aspects of proposed regulation 38.251(g). The Commission also invites specific comments on the following:

16. As noted above, proposed regulation 38.251(g) requires a DCM to notify Commission staff of a significant disruption to its electronic trading platform(s), while Commission regulation 38.1051(e) requires DCMs to notify the Commission in the event of significant systems malfunctions. Is the distinction between these two notification requirements sufficiently clear? If not, please explain.

17. Please describe any disruptive events that would potentially fall within the notification requirements of both proposed regulation 38.251(g) and Commission regulation 38.1051(e).

18. Is the Commission's description of whether a given disruption to a DCM's electronic trading platform(s) is ''significant'' for purposes of proposed regulation 38.251(g) sufficiently clear? If not, please explain.

19. Please describe circumstances in which it would be appropriate for a DCM to notify other DCMs about a significant market disruption on its trading platform(s). Should proposed regulation 38.251(g) include such a requirement?

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'')[62] requires federal agencies, in promulgating regulations, to consider the impact of those regulations on small entities, and to provide a regulatory flexibility analysis with respect to such impact. The regulations adopted herein will directly affect DCMs. The Commission previously determined that DCMs are not ''small entities'' for purposes of the RFA because DCMs are required to demonstrate compliance with a number of Core Principles, including principles concerning the expenditure of sufficient financial resources to establish and maintain an adequate self-regulatory program.[63] For these reasons, DCMs are not deemed ''small entities'' for purposes of the RFA, and the Chairman, on behalf of the Commission, hereby preliminarily certifies, pursuant to 5 U.S.C. 605(b), that the regulations will not have a significant economic impact on a substantial number of small entities.

Request for Comment

20. The Commission invites the public and other federal agencies to comment on the above determination.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'')[64] imposes certain requirements on federal agencies, including the Commission, in connection with conducting or sponsoring any ''collection of information,'' as defined by the PRA. Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number from the Office of Management and budget (''OMB'').[65] The PRA is intended, in part, to minimize the paperwork burden created for individuals, businesses, and other persons as a result of the collection of information by federal agencies, and to ensure the greatest possible benefit and utility of information created, collected, maintained, used, shared, and disseminated by or for the Federal Government.[66] The PRA applies to all information, regardless of form or format, whenever the Federal Government is obtaining, causing to be obtained, or soliciting information, and includes required disclosure to third parties or the public, of facts or opinions, when the information collection calls for answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons.[67]

This proposal, if adopted, would result in a collection of information within the meaning of the PRA, as discussed below. This proposed rulemaking contains collections of information for which the Commission has previously received control numbers from the Office of Management and Budget (''OMB''). The titles for these existing collections of information are: OMB control number 3038–0052, Core Principles and Other Requirements for DCMs (''OMB Collection 3038–0052'') and OMB control number 3038–0093, Provisions Common to Registered Entities (''OMB Collection 3038–0093'').

The Commission therefore is submitting this proposal to the OMB for its review in accordance with the PRA.[68] Responses to this collection of information would be mandatory. The Commission will protect any proprietary information according to the Freedom of Information Act and part 145 of the Commission's regulations.[69] In addition, section 8(a)(1) of the Commodity Exchange Act (''CEA'') strictly prohibits the Commission, unless specifically authorized by the CEA, from making public any ''data and information that would separately disclose the business transactions or market positions of any person and trade secrets or names of customers.'' [70] Finally, the Commission is also required to protect certain information contained

[62] 5 U.S.C. 601 *et seq.*

[63] *See* Policy Statement and Establishment of Definitions of ''Small Entities'' for Purposes of the Regulatory Flexibility Act, 47 FR 18618, 18619 (Apr. 30, 1982); *see also, e.g.,* DCM Core Principle 21 applicable to DCMs under section 735 of the Dodd-Frank Act.

[64] 44 U.S.C. 3501 *et seq.*

[65] *See* 44 U.S.C. 3507(a)(3); 5 CFR 1320.5(a)(3).

[66] *See* 44 U.S.C. 3501.

[67] *See* 44 U.S.C. 3502(3).

[68] *See* 44 U.S.C. 3507(d) and 5 CFR 1320.11.

[69] *See* 5 U.S.C. 552; *see also* 17 CFR part 145 (Commission Records and Information).

[70] 7 U.S.C. 12(a)(1).

in a government system of records according to the Privacy Act of 1974.[71]

1. OMB Collection 3038–0093—Provisions Common to Registered Entities

Proposed regulation 38.251(e) (''Risk Principle 1'') provides that DCMs must adopt and implement rules governing market participants subject to their respective jurisdictions to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading. As provided in the proposed Acceptable Practices in Appendix B to part 38, such rules must be reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading. Any such rules a DCM adopts pursuant to proposed regulation 38.251(e), must be submitted to the Commission in accordance with part 40 of the Commission's regulations. Specifically, a DCM would be required to submit such rules to the Commission in accordance with either: (1) Commission regulation 40.5, which provides procedures for the voluntary submission of rules for Commission review and approval; or (2) Commission regulation 40.6, which provides procedures for the self-certification of rules with the Commission. This information collection would be required for DCMs as needed, on a case-by-case basis. The Commission acknowledges, however, that there are various DCM practices in place today that may be consistent with proposed regulation 38.251(e), such as exchange-provided risk controls that address potential price distortions and related market anomalies. As such, it is possible that some DCMs would not be required to file new or amended rules to satisfy Risk Principle 1, if adopted.

Proposed Risk Principle 1, if adopted, would amend OMB Collection 3038–0093 by increasing the existing annual burden by 48 hours [72] for DCMs that would be required to comply with part 40 of the Commission's regulations, as described above. As a result, the revised total annual burden under this collection would be 720 hours.[73] Although the Commission believes that operational and maintenance costs for DCMs in proposed Risk Principle 1 will incrementally increase, these costs are expected to be de minimis.

OMB Collection 3038–0093 was created to cover the Commission's part 40 regulatory requirements for registered entities (including DCMs, swap execution facilities, derivatives clearing organizations, and swap data repositories) to file new or amended rules and product terms and conditions with the Commission.[74] OMB Control Number 3038–0093 covers all information collections in part 40, including Commission regulation 40.2 (Listing products by certification), Commission regulation 40.3 (Voluntary submission of new products for Commission review and approval), Commission regulation 40.5 (Voluntary submission of rules for Commission review and approval), and Commission regulation 40.6 (Self-certification of rules). The proposal is expected to modify the existing annual burden in OMB Collection 3038–0093 for complying with certain requirements in proposed Risk Principle 1, as estimated in aggregate below:

Estimated number of respondents: 15.

Estimated frequency/timing of responses: As needed.

Estimated number of annual responses per respondent: 2.

Estimated number of annual responses for all respondents: 30.

Estimated annual burden hours per response: 24.

Estimated total annual burden hours per respondent: 48.

Estimated total annual burden hours for all respondents: 720.

2. OMB Collection 3038–0052—Core Principles and Other Requirements for DCMs

Proposed regulation 38.251(g) (''Risk Principle 3'') requires a DCM to promptly notify Commission staff of any significant disruption to its electronic trading platform(s) and provide timely information on the cause and remediation of such disruption.[75] Under Risk Principle 3, such notification should include an email containing sufficient information to convey the nature of the disruption, and if known, its cause, and the remediation. The Commission recognizes that the specific cause of the disruption and the attendant remediation may not be known at the time of the disruption and may have to be addressed in a follow-up email or report. This information collection would be required for DCMs as needed, on a case-by-case basis.

Proposed Risk Principle 3, if adopted, would amend OMB Collection 3038–0052 by increasing the number of annual responses by 750 that may be filed by DCMs under the existing information collection. The proposed adoption of Risk Principle 3 would also incrementally increase the existing annual burden by 250 hours per DCM.[76] As a result, the revised total aggregate annual burden under this collection would be 3,750 hours.[77] Although the Commission believes that operational and maintenance costs for DCMs in proposed Risk Principle 3 will incrementally increase, these costs are expected to be de minimis.

OMB Collection 3038–0052 was created to cover regulatory requirements for DCMs under part 38 of the Commission's regulations.[78] OMB Control Number 3038–0052 covers all information collections in part 38, including Subpart A (General Provisions), Subparts B through X (the DCM core principles), as well as the related appendices thereto, including Appendix A (Form DCM), Appendix B (Guidance on, and Acceptable Practices in, Compliance with Core Principles), and Appendix C (Demonstration of Compliance That a Contract Is Not Readily Susceptible to Manipulation). The proposed amendments are expected to modify the existing annual burden in OMB Collection 3038–0052 for complying with certain requirements in Subpart E (Prevention of Market Disruption) of part 38, as estimated in aggregate below:

Estimated number of respondents: 15.

Estimated frequency/timing of responses: As needed.

Estimated number of annual responses per respondent: 50.

Estimated number of annual responses for all respondents: 750.

Estimated annual burden hours per response: 5.

Estimated total annual burden hours per respondent: 250.

Estimated total annual burden hours for all respondents: 3,750.

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[71] 5 U.S.C. 552a.

[72] The Commission estimates that proposed regulation 38.251(e) would require potentially 15 DCMs to make 2 filings with the Commission a year requiring approximately 24 hours each to prepare. Accordingly, the total burden hours for each DCM would be approximately 48 hours per year.

[73] The Commission estimates that the total aggregate annual burden hours for DCMs under proposed regulation 38.251(e) would be 720 hours based on each DCM incurring 48 burden hours (15 × 48 = 720).

[74] *See* 17 CFR part 40.

[75] *See supra* Section III.D (discussion of the Risk Principle 3).

[76] The Commission estimates that proposed regulation 38.251(g) would require potentially each DCM to make 50 reports with the Commission a year requiring approximately 5 hours each to prepare. Accordingly, the total burden hours for each DCM would be approximately 250 hours per year (50 × 5 = 250).

[77] The Commission estimates that the total aggregate annual burden hours for DCMs under proposed regulation 38.251(g) would be 3,750 hours based on each DCM incurring 250 burden hours (15 × 250 = 3,750).

[78] *See generally* 17 CFR part 38.

Estimated aggregate annual recordkeeping burden hours: 1,500.[79]

Request for Comment

The Commission invites the public and other federal agencies to comment on the proposed information collection requirements, including the following:

21. Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility;

22. Evaluate the accuracy of the estimated burden of the proposed information collection requirements, including the degree to which the methodology and the assumptions that the Commission employed were valid;

23. Are there ways to enhance the quality, utility, or clarity of the information proposed to be collected; and

24. Are there ways to minimize the burden of the proposed collections of information on DCMs, including through the use of appropriate automated, electronic, mechanical, or other technological information collection techniques.

The public and other federal agencies may submit comments directly to the Office of Information and Regulatory Affairs, OMB, by fax at (202) 395–6566 or by email at *OIRAsubmission@omb.eop.gov.* Please provide the Commission with a copy of submitted comments so that they can be summarized and addressed in the final rule. Refer to the **ADDRESSES** section of this document for comment submission instructions to the Commission. A copy of the supporting statements for the collections of information discussed above may be obtained by visiting *RegInfo.gov.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this release. Therefore, a comment to OMB is best assured of receiving full consideration if OMB (and the Commission) receives it within 30 days of publication of this document. Nothing in the foregoing affects the deadline enumerated above for public comment to the Commission on the proposed regulations.

C. Cost-Benefit Considerations

1. Introduction

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders.[80] Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors.

The baseline for this consideration of costs and benefits in this proposal is the monitoring and mitigation capabilities of DCMs, as governed by rules in current part 38 of CFTC regulations. Under these rules, DCMs are required to conduct real-time monitoring of all trading activity on its electronic trading platforms and identify disorderly trading activity and any market or system anomalies. Other sections of part 38 also require DCMs to establish and maintain risk control mechanisms to prevent and reduce the potential risk of price distortions and interruptions in orderly trading in markets, including, but not limited to, market restrictions that pause or halt trading in market conditions prescribed by the DCMs.[81] In particular, § 38.251(a) through (d) already require DCMs to use an effective real-time program to monitor and evaluate individual traders' market activity, as well as the general market data, in order to prevent and detect manipulative behavior and market disruptions. DCMs are also already required to demonstrate the ability to comprehensively and accurately reconstruct daily trading activity for the purposes of detecting trading abuses.

The Commission recognizes that the proposed rules may impose additional costs on DCMs and market participants. The Commission has endeavored to assess the expected costs and benefits of the proposed rulemaking in quantitative terms, including PRA-related costs, where possible. In situations where the Commission is unable to quantify the costs and benefits, the Commission identifies and considers the costs and benefits of the applicable proposed rules in qualitative terms. The lack of data and information to estimate those costs is attributable in part to the nature of the proposed rules and uncertainty about the potential responses of market participants to the implementation of the proposed rules. The Commission requests data and information from market participants and other commenters to allow it to better estimate the costs of the proposed rule.

2. Summary of Proposal

As discussed in more detail in the preamble above, the Commission considered taking a more prescriptive approach as an alternative to the proposed rules but decided to give more discretion to each DCM in terms of how to precisely define market disruptions and system anomalies as they relate to their particular markets. As a result, each DCM will have the flexibility to tailor the implementation of the proposed rules to best prevent, detect, and mitigate market disruptions or system anomalies in their respective markets. Consequently, the Commission believes that DCMs' tailored rules and their implementation will be less burdensome. Therefore the Commission proposes the following specific Risk Principles and associated Acceptable Practices applicable to DCM electronic trading.

a. Proposed Regulation 38.251(e)—Risk Principle 1

Proposed regulation 38.251(e)—Risk Principle 1—provides that a DCM must adopt and implement rules governing market participants subject to its jurisdiction to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading.

b. Proposed Regulation 38.251(f)—Risk Principle 2

Proposed regulation 38.251(f)—Risk Principle 2—provides that a DCM must subject all electronic orders to exchange-based pre-trade risk controls to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading.

c. Proposed Regulation 38.251(g)—Risk Principle 3

Proposed regulation 38.251(g)—Risk Principle 3—provides that a DCM must promptly notify Commission staff of a significant disruption to its electronic trading platform(s) and provide timely information on the causes and remediation.

d. Proposed Acceptable Practices for Proposed Regulations 38.251(e) and (f)

The proposed Acceptable Practices provide that to comply with regulation 38.251(e), the DCM must adopt and

[79] The Commission estimates that the total aggregate annual recordkeeping burden hours for DCMs under regulation 38.950 and 38.951 would be 1,500 hours based on each DCM incurring 100 burden hours (15 × 100 = 1,500).

[80] 7 U.S.C. 19(a).

[81] *See, e.g.,* Commission regulation 38.255, which currently requires DCMs to establish and maintain risk control mechanisms to prevent and reduce the potential risk of price distortions and market disruptions.

implement rules that are reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading. To comply with regulation 38.251(f), the DCM must subject all electronic orders to exchange-based pre-trade risk controls that are reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies.

Request for Comment

25. Do commenters believe that the Commission is correct in its determination that a prescriptive approach to proposed rules on risk controls and rules designed to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading would be too costly and burdensome?

26. Are there other alternative approaches with lower costs that the Commission should have considered? If so, please explain.

3. Costs

Existing Practices With Minimal Costs

DCMs' current risk management practices, particularly those implemented to comply with existing Commission regulations §§ 38.157, 38.251(c), 38.255, and 38.607, already may comply with the requirements of proposed rules 38.251(e) through (g). Specifically, while some DCMs might need to start collecting more detailed information from their market participants, the Commission believes most DCMs already have most of the information required to adopt and implement rules governing market participants subject to their respective jurisdiction in order to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading. The Commission also believes that DCMs have the means to acquire efficiently, and with potentially minimal cost, more information if needed. Moreover, DCMs currently monitor their markets and have rules to prevent and mitigate market disruptions or system anomalies, as required by proposed rule 38.251(e). The Commission also views many existing DCM pre-trade risk control practices to be consistent with the requirement in proposed regulation 38.251(f). Finally, DCMs already report to Commission staff certain interruptions in orderly trading in markets, including electronic trading halts and significant system malfunctions; cyber security incidents or targeted threats that actually or potentially jeopardize automated system operation, reliability, security, or capacity; and activations of a business continuity-disaster plan, as required by rule 38.1051(e).[82] Hence, the direct incremental cost of proposed rules 38.251(e) through (g) on DCMs is expected to be minimal.

New Costs To Adjust Existing Practices

To comply with rule 38.251(e), DCMs may be required to adjust their existing policies and procedures that involve increased monitoring of trading and communication patterns between market participants in their jurisdictions and the DCMs' matching engines.

Implementing these internal policies and procedures, and successfully communicating them to market participants, could involve costs for DCMs. Moreover, the Commission acknowledges that the DCM's monitoring efforts, and the associated required technologies, would need to be kept up to date, which could involve costs linked to the continual updating of these technologies and methodologies.

The Commission believes that DCMs may change their software to enable them to more efficiently capture additional information regarding participants subject to their jurisdiction to implement rules adopted pursuant to 38.251(e). The Commission expects the design, development, testing, and production release of a required software update to take 2,520 staff hours in total, which the Commission expects to be completed by more than one employee. To calculate the cost estimate for changes to DCM software, the Commission estimates the appropriate wage rate based on salary information for the securities industry compiled by the Department of Labor's Bureau of Labor Statistics (''BLS'').[83] Commission staff arrived at an hourly rate of $70.76 using figures from a weighted average of salaries and bonuses across different professions contained in the most recent BLS Occupational Employment and Wages Report (May 2019), multiplied by 1.3 to account for overhead and other benefits.[84] Commission staff chose this methodology to account for the variance in skillsets that may be used to plan, implement, and manage the required changes to DCM software. Using these estimates, the Commission would expect the software update to cost $178,313 per DCM. The Commission acknowledges that this is just an estimate and the actual cost of such a software update would depend on the current status of the specific DCM's information acquisition capabilities and the amount of additional information the DCM would have to collect as a result of proposed rule 38.251(e). To the extent that a DCM currently or partially captures the required information and data through its systems and technology, these costs would be incrementally lower.

The Commission acknowledges that any additional rules resulting from proposed regulation 38.251(e) will have to be submitted pursuant to part 40 when a DCM seeks to make amendments to its electronic trading risk requirements. The Commission expects a DCM to take an additional 48 hours annually (two submissions on average per year, 24 hours per submission) to submit these amendments to the Commission. In order to estimate the appropriate wage rate, the Commission used the salary information for the securities industry compiled by the BLS.[85] Commission staff arrived at an hourly rate of $89.89 using figures from a weighted average of salaries and bonuses across different professions contained in the most recent BLS Occupational Employment and Wages Report (May 2019) multiplied by 1.3 to account for overhead and other benefits.[86] The Commission estimates this indirect cost to each DCM to be $4,314.72 annually (48 × $89.89). To the

[82] The Commission notes that the notification requirement under Commission regulation 38.1051(e) does not include the planned operation of DCM stop logic, velocity logic, and circuit breaker functionality, which also support orderly markets.

[83] May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 523000—Securities, Commodity Contracts, and Other Financial Investments and Related Activities, available at *https://www.bls.gov/oes/current/naics4_523000.htm.*

[84] The Commission's estimated appropriate wage rate is a weighted national average of mean hourly wages for the following occupations (and their relative weight): ''computer programmer—industry: securities, commodity contracts, and other financial investment and related activities'' (25 percent); ''project management specialists and business operations specialists—industry: securities, commodity contracts, and other financial investment and related activities'' (25 percent); ''Software and Web Developers, Programmers, and Testers—industry: securities, commodity contracts, and other financial investment and related activities'' (25 percent); and ''Software Developers and Software Quality Assurance Analysts and Testers—industry: securities, commodity contracts, and other financial investment and related activities'' (25 percent).

[85] May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 523000—Securities, Commodity Contracts, and Other Financial Investments and Related Activities, available at *https://www.bls.gov/oes/current/naics4_523000.htm.*

[86] The Commission estimated appropriate wage rate is a weighted national average of mean hourly wages for the following occupations (and their relative weight): ''compliance officer—industry: securities, commodity contracts, and other financial investment and related activities'' (50 percent); and ''lawyer—legal services'' (50 percent). Commission staff chose this methodology to account for the variance in skill sets that may be used to accomplish the collection of information.

extent that a DCM currently has in place rules required under proposed 38.251(e), these costs would be incrementally lower.

The Commission can envision a scenario where a DCM might also need to update its trading systems to subject all electronic orders to exchange-based pre-trade risk controls to prevent, detect, and mitigate market disruptions or system anomalies as required by proposed rule 38.251(f). Depending on the amount of update required, the Commission anticipates the design, development, testing, and production release of the new trading system to take 8,480 staff hours in total, which the Commission expects to be covered by more than one employee. To calculate the cost estimate for updating a DCM's trading systems, the Commission estimates the appropriate wage rate based on salary information for the securities industry compiled by the BLS.[87] Commission staff arrived at an hourly rate of $70.76 using figures from a weighted average of salaries and bonuses across different professions contained in the most recent BLS Occupational Employment and Wages Report (May 2019) multiplied by 1.3 to account for overhead and other benefits.[88] Commission staff chose this methodology to account for the variance in skill sets that may be used to plan, implement, and manage the required update to a DCM's trading system. Using these estimates, the Commission would expect the trading system update to cost $600,036 to a DCM. The Commission would like to emphasize that this is just an estimate and the actual cost could be higher or lower. The cost may also vary across DCMs, as each DCM has the flexibility to apply the specific controls that the DCM deems reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies. In addition, the Commission would further note that to the extent that a DCM currently or partially has in place pre-trade risk controls consistent with proposed 38.251(f), these costs would be incrementally lower.

Proposed regulation 38.251(g) would require a DCM to notify promptly Commission staff of a significant disruption to its electronic trading platform(s) and provide timely information on the causes and remediation. The Commission expects that there may be incremental costs to DCMs from proposed regulation 38.251(g) in the form of analysis regarding which disruptions could be significant enough to report, maintain, and archive the relevant data, as well as the costs associated with the act of reporting the disruptions. The Commission currently expects every DCM to have the necessary means to communicate with the Commission promptly, and therefore, does not expect any additional communication costs. The Commission expects DCMs to incur a minimal cost in determining what a significant disruption could be and preparing information on its causes and remediation. The Commission does not expect this cost to be significant, because the Commission believes DCMs should already have the means necessary to identify the causes of market disruptions and have plans for remediation. To the extent that complying with regulation 38.251(g) requires a DCM to incur additional recordkeeping and reporting burdens, the Commission estimates these additional recordkeeping requirements to require approximately 100 hours per DCM per year and the additional reporting requirements to require approximately 250 hours per DCM per year (five hours per report and an estimated 50 reports additionally per DCM). In calculating the cost estimates for recordkeeping and reporting, the Commission estimates the appropriate wage rate based on salary information for the securities industry compiled by the BLS.[89] For the reporting cost, Commission staff arrived at an hourly rate of $76.44 using figures from a weighted average of salaries and bonuses across different professions contained in the most recent BLS Occupational Employment and Wages Report (May 2019) multiplied by 1.3 to account for overhead and other benefits.[90] In calculating the cost estimate for recordkeeping, the Commission staff arrived at an hourly rate of $71.019 using figures from the most recent BLS Occupational Employment and Wages Report (May 2019) multiplied by 1.3 to account for overhead and other benefits.[91] The Commission estimates the cost for additional recordkeeping to a DCM to be $7,101.90 (100 × $71.019) annually and the cost for additional reporting to a DCM to be $19,110 (250 × $76.44) annually. As noted above, the exact cost will depend on the software update and could be higher or lower than the Commission's estimate.

To the extent that DCMs would need to update their rules and internal processes to comply with regulation 38.251(e) through (g) and the associated Acceptable Practices, the Commission expects that DCMs also may need to update or supplement their compliance program, which would involve additional costs. However, the Commission does not expect these costs to be significant. The Commission believes that some DCMs may need to hire an additional full-time compliance staff member to address the additional compliance needs associated with the proposed regulation. Assuming that the average annual salary of each compliance officer is $94,705, the Commission estimates the incremental annual compliance costs to a DCM that needs to hire an additional compliance officer to be $119,340.[92] However, the Commission notes that the exact compliance needs may vary across DCMs, and some DCMs may already have adequate compliance programs that can handle any rule updates and

[87] May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 523000—Securities, Commodity Contracts, and Other Financial Investments and Related Activities, available at *https://www.bls.gov/oes/current/naics4_523000.htm.*

[88] The Commission's estimated appropriate wage rate is a weighted national average of mean hourly wages for the following occupations (and their relative weight): ''computer programmer—industry: securities, commodity contracts, and other financial investment and related activities'' (25 percent); ''project management specialists and business operations specialists—industry: securities, commodity contracts, and other financial investment and related activities'' (25 percent); ''Software and Web Developers, Programmers, and Testers—industry: securities, commodity contracts, and other financial investment and related activities'' (25 percent); and ''Software Developers and Software Quality Assurance Analysts and Testers—industry: securities, commodity contracts, and other financial investment and related activities'' (25 percent).

[89] May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 523000—Securities, Commodity Contracts, and Other Financial Investments and Related Activities, available at *https://www.bls.gov/oes/current/naics4_523000.htm.*

[90] The Commission estimated appropriate wage rate is a weighted national average of mean hourly wages for the following occupations (and their relative weight): ''computer programmer—industry: securities, commodity contracts, and other financial investment and related activities'' (25 percent); ''compliance officer—industry: securities, commodity contracts, and other financial investment and related activities'' (50 percent); and ''lawyer—legal services'' (25 percent). Commission staff chose this methodology to account for the variance in skill sets that may be used to accomplish the required reporting.

[91] The Commission estimated appropriate wage rate is the mean hourly wages for ''database administrators and architects.'' Commission staff chose this methodology to account for the variance in skill sets that may be used to accomplish the collection of information.

[92] In calculating this cost estimate for reporting, the Commission estimates the appropriate annual wage for a compliance officer based on salary information for the securities industry compiled by the BLS. Commission staff used the annual wage of $91,800, which reflects the average annual salary for a compliance officer contained in the most recent BLS Occupational Employment and Wages Report (May 2019), and multiplied it by 1.3 to account for overhead and other benefits.

internal processes required to comply with regulation 38.251(e) through (g), and therefore the actual compliance costs may be higher or lower than the Commission's estimates.

Cost of Periodically Updating Risk Management Practices

The Commission expects the trading methods and technologies of market participants to change over time, requiring DCMs to adjust their rules accordingly. As trading methodologies and connectivity measures evolve, it is expected that new ways of potential market disruptions and system anomalies could surface. To that end, the Commission believes full compliance would require a DCM to implement periodic evaluation of its entire electronic trading marketplace and updates of the exchange-based pre-trade risk controls to prevent, detect, and mitigate market disruptions or system anomalies, as well as updates of the appropriate definitions of market disruptions and system anomalies. Therefore, rules imposed as a result of proposed regulation 38.251(e) through (g) would need to be flexible and fluid, and potentially updated as needed, which may involve additional costs. Moreover, such rule changes would result in a cost increase associated with the rise in the number of rule filings that DCMs would have to prepare and submit to the Commission.

Costs to Market Participants

To the extent the rules adopted by DCMs as a result of the proposed regulation change frequently, the Commission can envision a situation where market participants would need to adjust to new rules frequently. While these adjustments might carry some costs for market participants, such as potential added delays to their trading activity due to added pre-trade controls, the Commission expects these changes to be communicated to the market participants by DCMs with enough implementation time so as to minimize the burden on market participants and their trading strategies. Moreover, to the extent a DCM's policies and procedures require market participants to report changes to their connection processes, trading strategies, or any other adjustments the DCM deems required, there could be some cost to the market participants. Finally, market participants may feel the need to upgrade their risk management practices as a response to DCMs' updated risk management practices driven by the proposed rules. The Commission recognizes that part of the costs to market participants might also come from needing to update their systems and potentially adjust the software they use for risk management, trading, and reporting. To the extent that market participants currently comply with DCM rules and regulations regarding pre-trade risk controls and market disruption protocols, these costs may be somewhat mitigated under the proposal.

Regulatory Arbitrage

The proposed rules offer DCMs the flexibility to address market disruptions and system anomalies as they relate to their particular markets and market participants' trading activities. Similarly, DCMs are also given the flexibility to decide how to apply the proposed requirements in their respective markets. This flexibility could result in differences across DCMs, potentially contributing to regulatory arbitrage. For example, DCMs' practices could differ in the information collected from market participants; the rules applied to prevent, detect, and mitigate market disruptions or system anomalies; and the intensity of pre-trade controls. The parameters for establishing disruptive behavior could be defined differently by the various DCMs, which might lead to differing levels of exchange-based pre-trade risk controls. The Commission acknowledges that to the extent there is potential for market participants to choose between DCMs, those DCMs with lower information collection requirements and potentially less stringent pre-trade risk controls could appear more attractive to certain market participants. All or some of these factors could create the potential for market participants to move their trading from DCMs with potentially more stringent risk controls to DCMs with less stringent controls, which could cost certain DCMs business. While the Commission recognizes that this kind of regulatory arbitrage could cause liquidity to move from one DCM to another, potentially impairing (benefiting) the price discovery of the contract with reduced (increased) liquidity, the Commission does not expect this to occur with any real frequency. First, the Commission notes that liquidity for a given contract in futures markets tends to concentrate in one DCM. This means that futures markets are less susceptible to this type of regulatory arbitrage. Second, while an individual DCM decides the exchange-based pre-trade risk controls for its markets, those risk controls must be effective. The Commission does not believe that differences in the application of the proposed regulation across DCMs would be substantial enough to induce market participants to switch to trading at a different DCM, even if there were two DCMs trading similar enough contracts. For example, DCMs currently apply various pre-trade controls to comply with rule 38.255 requirements for risk controls for trading, but the Commission does not have any evidence that DCMs compete on pre-trade controls. The Commission expects DCMs to approach the setting of their practices to comply with this proposed regulation in a similar manner.

Request for Comment

27. Are the costs the Commission considers in the cost-benefit considerations section reasonable? If not, please explain.

28. Do DCMs currently collect most of the information required from market participants in order to comply with rule 38.251(e)? If not, what are the associated expected costs?

29. Are there other costs the Commission should have included in the cost-benefit considerations section? If so, please explain.

30. Are the software update estimates the Commission considers reasonable? If not, please explain.

31. Should the Commission make use of other sources for enumerating costs associated with the proposed rule? If so, please explain.

4. Benefits

Minimize Disruptive Behaviors Associated With Electronic Trading and Ensure Sound Financial Markets

The Commission believes that the proposed rules are crucial for the integrity and resilience of financial markets, as the proposed rules would ensure that DCMs have the ability to prevent, detect and mitigate most, if not all, disruptive behaviors associated with electronic trading. The proposed changes to regulation 38.251(e) require DCMs to adopt and implement rules governing market participants subject to its jurisdiction such that market disruptions or system anomalies associated with electronic trading can be minimized. This would allow markets to operate smoothly and to continue functioning as efficient platforms for risk transfer, as well as allowing for healthy price discovery.

The Commission expects proposed regulation 38.251(f) to subject all electronic orders to a DCM's exchange-based pre-trade risk controls. The Commission expects this to benefit the markets as well as the market participant sending orders to the exchanges. First, by preventing orders that could cause market disruptions or

system anomalies through exchange-based pre-trade risk controls, proposed regulation 38.251(f) allows the markets to operate orderly and efficiently. This benefits traders in the markets, market participants utilizing price discovery in the markets, as well as traders in related markets. Second, proposed regulation 38.251(f) provides market participants sending orders to a DCM with an additional layer of protection through the implementation of exchange-based pre-trade risk controls. If an unintentional set of messages were to breach the risk controls of market participants and FCMs, proposed regulation 38.251(f) could prevent those messages from reaching a DCM and potentially resulting in unwanted transactions. This benefits the market participants, as well as their FCMs, by saving them from the obligation of unwanted and unintended transactions.

Proposed regulation 38.251(g) ensures that significant disruptions will be communicated to the Commission staff promptly, as well as their causes and eventual remediation. The Commission believes proposed regulation 38.251(g) will benefit the markets and market participants by strengthening their financial soundness and promoting the resiliency of derivatives markets by allowing the Commission to stay informed of any potential market disruptions effectively and promptly. If needed, the Commission's timely action in the face of market disruptions could help markets recover faster and stronger.

Finally, proposed regulations 38.251(e) through (g) are likely to benefit the public by promoting sound risk management practices across market participants and preserving the financial integrity of markets so that markets can continue to fulfill their price discovery role.

Value of Flexibility Across DCMs

The Commission believes that DCMs have markets with different trading structures and participants with varying trading patterns. It is possible that what one DCM deems to be the paramount disruptive behavior for its market could be different for another DCM. The Commission's principles-based approach to proposed regulations 38.251(e) and (f) allows DCMs the flexibility to impose the most efficient and effective rules and pre-trade risk controls for their respective jurisdictions. The Commission believes such flexibility, particularly through the proposed Acceptable Practices, benefits DCMs by allowing them to adopt and implement effective and efficient measures reasonably designed to achieve the objectives of the Risk Principles. Without such flexibility, DCMs would need to comply with prescriptive rules that may not be as effective in preventing disruptive trading and market anomalies and that may potentially involve higher compliance costs.

Direct Benefits to Market Participants

Proposed rule 38.251(e) requires DCMs to adopt and implement rules to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading. To this end, the proposed Acceptable Practices for proposed rule 38.251(f) would enable DCMs to subject all electronic orders to exchange-based pre-trade risk controls that are reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies. This approach will assist in preventing or mitigating market disruptions and protect the effectiveness of financial markets to continue providing the services of risk transfer and price transparency to all market participants. Moreover, the Commission believes that requiring DCMs to design these rules could incentivize market participants themselves to strengthen their own risk management practices as a response to potential changes in pre-trade risk controls that all electronic orders will be subject to.

Facilitate Commission Oversight

The Commission believes the implementation of the proposed rules would facilitate the Commission's capability to effectively monitor the market. Moreover, proposed rule 38.251(g) will result in DCMs informing the Commission promptly of any significant market disruptions and remediation plans. The Commission believes this would allow it to also take steps to contain a disruption and prevent the disruption from impacting other markets or market participants. Thus, the proposed rules would facilitate the Commission's oversight and its ability to monitor and assess market disruptions across all DCMs.

Finally, the Commission expects that the proposed rule would better incentivize DCMs to recognize market disruptions and examine remediation plans in a timely fashion.

Request for Comment

32. Are the benefits the Commission considers in the cost-benefit considerations section reasonable? If not, please explain.

33. Are there other benefits the Commission should have included in the cost-benefit considerations section? If so, please explain.

5. 15(a) Factors

a. Protection of Market Participants and the Public

Proposed rules 38.251(e) through (g) are intended to protect market participants and the public from potential market disruptions due to electronic trading. The proposal is expected to benefit market participants and the public by requiring DCMs to adopt and implement rules addressing the market disruptions and system anomalies associated with electronic trading, subject all electronic orders to specifically-designed exchange-based pre-trade risk controls, and promptly report the causes and remediation of significant market disruptions. All of these measures create a safer marketplace for market participants to continue trading without major interruptions and allow the public to benefit from the information generated through a well-functioning marketplace.

b. Efficiency, Competitiveness, and Financial Integrity of DCMs

The Commission believes that proposed rules 38.251(e) through (g) will enhance the financial integrity of DCMs by requiring DCMs to implement rules and risk controls to address market disruptions and system anomalies associated with electronic trading. However, the Commission also acknowledges that market participants' efficiency of trading might be hindered due to their orders taking longer to reach the matching engine as a result of additional pre-trade risk controls. In addition, the Commission can envision a scenario where the flexibility provided to DCMs in designing and implementing rules to prevent, detect, and mitigate market disruptions and system anomalies, and the differences between the updated pre-trade risk controls and existing DCM risk control rules, could potentially lead to regulatory arbitrage between DCMs. To the extent that there are significant differences in those practices set by competing DCMs, market participants might choose to trade in the DCM with least stringent rules if competing DCMs offer the same or relatively similar products. The Commission acknowledges that competitiveness across DCMs might be hurt as a result. However, as discussed above, the Commission does not believe that differences in the application of the proposed regulation across DCMs would be substantial enough to induce market participants to switch to trading at a different DCM, even if there were two DCMs trading similar enough contracts.

c. Price Discovery

The Commission expects price discovery to improve as a result of proposed rules 38.251(e) through (g), especially due to improved market functioning through the implementation of targeted pre-trade risk controls and rules. The Commission expects the new regulation to assist with the prevention and mitigation of market disruptions due to electronic trading, leading markets to provide more consistent price discovery services. However, as noted above, adoption and implementation of rules pursuant to 38.251(e) and pre-trade risk controls implemented by DCMs could be different across DCMs. As a result, the improvements in price discovery across DCMs markets are not likely to be uniform.

d. Sound Risk Management Practices

The Commission expects proposed rules 38.251(e) through (g) to help promote and ensure better risk management practices of both DCMs and their market participants. The Commission expects DCMs and market participants to focus on, and potentially update, their risk management practices. Additionally, the Commission believes that the requirement for DCMs to notify the Commission staff regarding the cause of a significant disruption to their respective electronic trading platforms would also provide reputational incentives for both DCMs and their market participants to focus on, and improve, risk management practices.

e. Other Public Interest Considerations

The Commission does not expect proposed rules 38.251(e) through (g) to have any significant costs or benefits associated with any other public interests.

D. Antitrust Considerations

Section 15(b) of the CEA requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the purposes of CEA, in issuing any order or adopting any Commission rule or regulation (including any exemption under section 4(c) or 4c(b)), or in requiring or approving any bylaw, rule, or regulation of a contract market or registered futures association established pursuant to section 17 of the CEA.[93]

The Commission believes that the public interest to be protected by the antitrust laws is generally to protect competition.

[93] 7 U.S.C. 19(b).

The Commission has considered the proposal to determine whether it is anticompetitive and has preliminarily identified no anticompetitive effects. The Commission requests comment on whether the proposal is anticompetitive and, if it is, what the anticompetitive effects are.

Because the Commission has preliminarily determined that the proposal is not anticompetitive and has no anticompetitive effects, the Commission has not identified any less anticompetitive means of achieving the purposes of the CEA. The Commission requests comment on whether there are less anticompetitive means of achieving the relevant purposes of the CEA that would otherwise be served by adopting the proposal.

Request for Comment

34. Does this proposal implicate any other specific public interest to be protected by the antitrust laws?

List of Subjects in 17 CFR Part 38

Commodity futures, Designated contract markets, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 38 as follows:

PART 38—DESIGNATED CONTRACT MARKETS

■ 1. The authority citation for part 38 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 6, 6a, 6c, 6d, 6e, 6f, 6g, 6i, 6j, 6k, 6l, 6m, 6n, 7, 7a–2, 7b, 7b–1, 7b–3, 8, 9, 15, and 21, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376.

■ 2. In § 38.251, republish introductory text and add paragraphs (e) through (g) to read as follows:

§ 38.251 General requirements.

A designated contract market must:

* * * * *

(e) Adopt and implement rules governing market participants subject to its jurisdiction to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading;

(f) Subject all electronic orders to exchange-based pre-trade risk controls to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading; and

(g) Promptly notify Commission staff of any significant disruptions to its electronic trading platform(s) and provide timely information on the causes and remediation.

■ 3. In appendix B to part 38, republish the text of Core Principle 4 of section 5(d) of the Act: Prevention of Market Disruption and add paragraph (b)(6) to read as follows:

Appendix B to Part 38—Guidance on, and Acceptable Practices in, Compliance with Core Principles

* * * * *

Core Principle 4 of section 5(d) of the Act: PREVENTION OF MARKET DISRUPTION.—The board of trade shall have the capacity and responsibility to prevent manipulation, price distortion, and disruptions of the delivery or cash-settlement process through market surveillance, compliance, and enforcement practices and procedures, including—

(A) Methods for conducting real-time monitoring of trading; and

(B) Comprehensive and accurate trade reconstructions.

(a) *Guidance.* The detection and prevention of market manipulation, disruptions, and distortions should be incorporated into the design of programs for monitoring trading activity. Monitoring of intraday trading should include the capacity to detect developing market anomalies, including abnormal price movements and unusual trading volumes, and position-limit violations. The designated contract market should have rules in place that allow it broad powers to intervene to prevent or reduce market disruptions. Once a threatened or actual disruption is detected, the designated contract market should take steps to prevent the disruption or reduce its severity.

(2) *Additional rules required.* A designated contract market should adopt and enforce any additional rules that it believes are necessary to comply with the requirements of subpart E of this part.

(b) *Acceptable Practices*—(1) *General Requirements.* Real-time monitoring for market anomalies and position-limit violations are the most effective, but the designated contract market may also demonstrate that it has an acceptable program if some of the monitoring is accomplished on a T + 1 basis. An acceptable program must include automated trading alerts to detect market anomalies and position-limit violations as they develop and before market disruptions occur or become more serious. In some cases, a designated contract market may demonstrate that its manual processes are effective.

(2) *Physical-delivery contracts.* For physical-delivery contracts, the designated contract market must demonstrate that it is monitoring the adequacy and availability of the deliverable supply, which, if such information is available, includes the size and ownership of those supplies and whether such supplies are likely to be available to short traders and saleable by long traders at the market value of those supplies under normal cash marketing conditions. Further, for physical-delivery contracts, the designated contract market must continually monitor the appropriateness of a contract's terms and conditions, including the delivery instrument, the delivery locations and

location differentials, and the commodity characteristics and related differentials. The designated contract market must demonstrate that it is making a good-faith effort to resolve conditions that are interfering with convergence of its physical-delivery contract to the price of the underlying commodity or causing price distortions or market disruptions, including, when appropriate, changes to contract terms.

(3) *Cash-settled contracts.* At a minimum, an acceptable program for monitoring cash-settled contracts must include access, either directly or through an information-sharing agreement, to traders' positions and transactions in the reference market for traders of a significant size in the designated contract market near the settlement of the contract.

(4) *Ability to obtain information.* With respect to the designated contract market's ability to obtain information, a designated contract market may limit the application of the requirement to keep and provide such records only to those that are reportable under its large-trader reporting system or otherwise hold substantial positions.

(5) *Risk controls for trading.* An acceptable program for preventing market disruptions must demonstrate appropriate trade risk controls, in addition to pauses and halts. Such controls must be adapted to the unique characteristics of the markets to which they apply and must be designed to avoid market disruptions without unduly interfering with that market's price discovery function. The designated contract market may choose from among controls that include: Pre-trade limits on order size, price collars or bands around the current price, message throttles, and daily price limits, or design other types of controls. Within the specific array of controls that are selected, the designated contract market also must set the parameters for those controls, so long as the types of controls and their specific parameters are reasonably likely to serve the purpose of preventing market disruptions and price distortions. If a contract is linked to, or is a substitute for, other contracts, either listed on its market or on other trading venues, the designated contract market must, to the extent practicable, coordinate its risk controls with any similar controls placed on those other contracts. If a contract is based on the price of an equity security or the level of an equity index, such risk controls must, to the extent practicable, be coordinated with any similar controls placed on national security exchanges.

(6) *Market disruptions and system anomalies associated with electronic trading.* To comply with § 38.251(e), the contract market must adopt and implement rules that are reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading. To comply with § 38.251(f), the contract market must subject all electronic orders to exchange-based pre-trade risk controls that are reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies.

* * * * *

Issued in Washington, DC, on June 29, 2020, by the Commission.

Christopher Kirkpatrick,

Secretary of the Commission.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Electronic Trading Risk Principles—Commission Voting Summary, Chairman's Statement, and Commissioners' Statements

Appendix 1—Commission Voting Summary

On this matter, Chairman Tarbert and Commissioners Quintenz, Stump, and Berkovitz voted in the affirmative. Commissioner Behnam voted in the negative.

Appendix 2—Supporting Statement of Chairman Heath P. Tarbert

The mission of the CFTC is to promote the integrity, resilience, and vibrancy of U.S. derivatives markets through sound regulation. We cannot achieve this mission if we rest on our laurels—particularly in relation to the ever evolving technology that makes U.S. derivatives markets the envy of the world. What is sound regulation today may not be sound regulation tomorrow.

I am reminded of the paradoxical observation of Giuseppe di Lampedusa in his prize-winning novel, The Leopard:

If we want things to stay as they are, things will have to change.[1]

While the novel focuses on the role of the aristocracy amid the social turbulence of 19th century Sicily, its central thesis—that achieving stability in changing times itself requires change—can be applied equally to the regulation of rapidly changing financial markets.

Today we are voting on a proposal to address the risk of disruptions to the electronic markets operated by futures exchanges. The risks involved are significant; disruptions to electronic trading systems can prevent market participants from executing trades and managing their risk. But how we address those risks—and the implications for the relationship between the Commission and the exchanges we regulate—is equally significant.

The Evolution of Electronic Trading

A floor trader from the 1980s and even the 1990s would scarcely recognize the typical futures exchange of the 21st Century. The screaming and shouting of buy and sell orders reminiscent of the film *Trading Places* has been replaced with silence, or perhaps the monotonous humming of large data centers. For over the past two decades, our markets have moved from open outcry trading pits to electronic platforms. Today, 96 percent of trading occurs through electronic systems, bringing with it the price discovery and hedging functions foundational to our markets.

By and large, this shift to electronic trading has benefited market participants. Spreads have narrowed,[2] liquidity has improved,[3] and transaction costs have dropped.[4] And the most unexpected benefit is that electronic markets have been able to stay open and function smoothly during the Covid-19 lockdowns. By comparison, traditional open outcry trading floors such as options pits and the floor of the New York Stock Exchange were forced to close for an extended time. Without the innovation of electronic trading, our financial markets would almost certainly have seized up and suffered even greater distress.

But like any technological innovation, electronic trading also creates new and unique risks. Today's proposal is informed by examples of disruptions in electronic markets caused by both human error as well as malfunctions in automated systems—disruptions that would not have occurred in open outcry pits. For instance, ''fat finger'' orders mistakenly entered by people, or fully automated systems inadvertently flooding matching engines with messages, are two sources of market disruptions unique to electronic markets.

Past CFTC Attempts To Address Electronic Trading Risks

The CFTC has considered the risks associated with electronic trading during much of the last decade. Seven years ago, a different set of Commissioners issued a concept release asking for public comment on what changes should be made to our regulations in light of the novel issues raised by electronic trading. Out of that concept release, the Commission later proposed Regulation AT. For all its faults, Regulation AT drove a very healthy discussion about the risks that should be addressed and the best way to do so.

Regulation AT was based on the assumption that automated trading, a subset of electronic trading, was inherently riskier than other forms of trading. As a result, Regulation AT sought to require certain automated trading firms to register with the Commission notwithstanding that they did not hold customer funds or intermediate customer orders. Most problematically, Regulation AT also would have required those firms to produce their source code to the agency upon request and without subpoena.

Regulation AT also took a prescriptive approach to the types of risk controls that exchanges, clearing members, and trading firms would be required to place on order messages. But this list was set in 2015. In effect, Regulation AT would have frozen in time a set of controls that all levels of market

[1] Giuseppe Tomasi di Lampedusa, *The Leopard* (Everyman's Library Ed. 1991) at p. 22.

[2] Frank, Julieta and Philip Garcia, ''Bid-Ask Spreads, Volume, and Volatility: Evidence from Livestock Markets,'' *American Journal of Agricultural Economics*, Vol. 93, Issue 1, page 209 (January 2011).

[3] Henderschott, Terrence, Charles M. Jones, and Albert K. Menkveld, ''Does Algorithmic Trading Improve Liquidity?'' *Journal of Finance*, Volume 66, Issue 1, page 1 (February 2011).

[4] Onur, Esen and Eleni Gousgounis, ''The End of an Era: Who Pays the Price when the Livestock Futures Pits Close?'', Working paper, Commodity Futures Trading Commission Office of the Chief Economist.

operators and market participants would have been required to place on trading. Since that list was proposed, financial markets have faced their highest volatility on record and futures market volumes have increased by over 50 percent.[5] Improvements in technology and computer power have been profound—Moore's Law would predict that computing power would have increased at least ten-fold in that time.[6] Of course, I commend my predecessors for focusing on the risks that electronic trading can bring. But times change, and Regulation AT would not have changed with them.

An Evolving CFTC for Evolving Markets

In withdrawing Regulation AT, the CFTC is consciously moving away from the registration requirements and source code production. But in voting to advance the Risk Principles proposal outlined further below, the CFTC is committing to address risk posed by electronic trading while strengthening our longstanding principles-based approach to overseeing exchanges.

The markets we regulate are changing. To maintain our regulatory functions, the CFTC must either halt that change or change our agency. Swimming against the tide of developments like electronic markets is not an option, nor should it be. The markets exist to serve the needs of market participants, not the regulator. If a technological change improves the functioning of the markets, we should embrace it. In fact, one of this agency's founding principles is that CFTC should ''foster responsible innovation.'' [7] Applying this reasoning alongside the overarching theme of *The Leopard* leads us to a single conclusion: As our markets evolve, the only real course of action is to ensure that the CFTC's regulatory framework evolves with it.

The Need for Principles-Based Regulation

So then how do we as a regulator change with the times while still fulfilling our statutory role overseeing U.S. derivatives markets? I recently published an article setting out a framework for addressing situations such as this.[8] I believe that principles-based regulations can bring simplicity and flexibility while also promoting innovation when applied in the right situations. Such an approach can also create a better supervisory model for interaction between the regulator and its regulated firms—but only so long as that oversight is not toothless.

There are a variety of circumstances in which I believe principles-based regulation would be most effective. Regulations on how exchanges manage the risks of electronic trading are a prime example. This is about risk management practices at sophisticated institutions subject to an established and ongoing supervisory relationship. But it is also an area where regulated entities have greater understanding than the regulator about the risks they face and greater knowledge about how to address those risks. As a result, exchanges need flexibility in how they manage risks as they constantly evolve.

At the same time, principles-based regulation is not ''light touch'' regulation. Without the ability to monitor compliance and enforce the rules, principles-based regulation would be toothless. Principles-based regulation of exchanges can work because the CFTC and the exchanges have constant interaction that engenders a degree of mutual trust. The CFTC—as overseen by our five-member Commission—has tools to monitor how the exchanges implement principles-based regulations through reviews of license applications and rule changes, as well as through periodic examinations and rule enforcement reviews.

Monitoring compliance alone is not enough. The regulator also needs the ability to enforce against non-compliance. Principles-based regimes ultimately give discretion to the regulated entity to find the best way to achieve a goal, so long as that method is objectively reasonable. To that end, the CFTC has a suite of tools to require changes through formal action, escalating from denial of rule change requests, to enforcement actions, to license revocations. The CFTC consistently needs to address the effectiveness and appropriateness of these levers to make sure the exchanges are meeting their regulatory objectives. And given that exchanges will be judged on a reasonableness standard, it must be the Commission itself—based on a recommendation from CFTC staff [9]—who ultimately decides whether an exchange has been objectively unreasonable in complying with our principles.

Proposed Risk Principles for Electronic Trading

This brings us to today's proposed Risk Principles. The proposal centers on a straightforward issue that I think we can all agree is important for our regulations to address. Namely, the proposal requires exchanges to take steps to prevent, detect, and mitigate market disruptions and system anomalies associated with electronic trading.

The disruptions we are concerned about can come from any number of causes, including:

Excessive messages,
fat finger orders, or
the sudden shut off of order flow from a market maker.

The key attribute of the disruptions addressed in this proposal is that they arise because of electronic trading.

To be sure, our current regulations do require exchanges to address market disruptions. But the focus of those rules has generally been on disruptions caused by sudden price swings and volatility. In effect, the proposed Risk Principles would expand the term ''market disruptions'' to cover instances where market participants' ability to access the market or manage their risks is negatively impacted by something other than price swings. This could include slowdowns or closures of gateways into the exchange's matching engine caused by excessive messages submitted by a market participant. It could also include instances when a market maker's systems shut down and the market maker stops offering quotes.

As noted in the preamble to the proposal, exchanges have worked diligently to address emerging risks associated with electronic trading. Different exchanges have put in place rules such as messaging limits and penalties when messages exceed filled trades by too large a ratio. Exchanges also may conduct due diligence on participants using certain market access methods and may require systems testing ahead of trading through those methods.

It is not surprising that exchanges have developed rules and risk controls that comport with our proposed Risk Principles. The Commission, exchanges, and market participants have a common interest in ensuring that electronic markets function properly. Moreover, this is an area where exchanges are likely to possess the best understanding of the risks presented and have control over how their own systems operate. As a result, exchanges have the incentive and the ability to address the risks arising from electronic trading. Principles-based regulations in this area will ensure that the exchanges have reasonable discretion to adjust their rules and risk controls as the situation dictates, not as the regulator dictates.

The three Risk Principles encapsulate this approach. First, exchanges must have rules to prevent, detect, and mitigate market disruptions and system anomalies associated with electronic trading. In other words, an exchange should take a macro view when assessing potential market disruptions, which can include fashioning rules applicable to all traders governing items such as onboarding, systems testing, and messaging policies. Second, exchanges must have risk controls on all electronic orders to address those same concerns. Third, exchanges must notify the CFTC of any significant market disruptions and give information on mitigation efforts.

Importantly, implementation of the Risk Principles will be subject to a reasonableness standard. The proposed Acceptable Practices clarify that an exchange would be in compliance if its rules and its risk controls are reasonably designed to meet the objectives of preventing, detecting, and

[5] Futures Industry Association, ''A record year for derivatives,'' (March 5, 2019), available at *https://www.fia.org/articles/record-year-derivatives.*

[6] ''Moore's Law'' predicts that the number of transistors in an integrated circuit doubles about every two years, and has held generally true since 1965. *See generally* Sneed, Annie, ''Moore's Law Keeps Going, Defying Expectations,'' *Scientific American* (May 19, 2015).

[7] Commodity Exchange Act, section 3(b), 7 U.S.C. 3(b).

[8] Tarbert, Heath P., ''Rules for Principles and Principles for Rules: Tools for Crafting Sound Financial Regulation,'' Harv. Bus. L. Rev. (June 15, 2020). Vol. 10 (*https://www.hblr.org/volume-10-2019-2020/*).

[9] CFTC Staff conduct regular examinations and reviews of our registered entities, including exchanges and clearinghouses. As part of those examinations and reviews, Staff may identify issues of material non-compliance with regulations as well as recommendations to bring an entity into compliance. Ultimately, however, the Commission itself must accept an examination report or rule enforcement review report before it can become final, including any findings of non-compliance. Likewise, Staff are asked to make recommendations regarding license applications, reviews of new products and rules, and a variety of other Commission actions, although ultimate authority lies with the Commission.

mitigating market disruptions and system anomalies. The Commission will have the ability to monitor how the exchanges are complying with the Principles, and will have avenues through Commission action to sanction non-compliance.

Framework for Future Regulation

I hope that today's Risk Principles proposal will serve as a framework for future CFTC regulations. Electronic trading presents a prime example of where principles-based regulation—as opposed to prescriptive rule sets—is more likely to result in sound regulation over time. Through thoughtful analysis of the regulatory objective we aim to achieve, the nature of the market and technology we are addressing, the sophistication of the parties involved, and the nature of the CFTC's relationship with the entity being regulated, we can identify what areas are best for a prescriptive regulation or a principles-based regulation.[10] In the present context, a principles-based approach—setting forth concrete objectives while affording reasonable discretion to the exchanges—provides flexibility as electronic trading practices evolve, while maintaining sound regulation. In sum, it recognizes that things will have to change if we want things to stay as they are.[11]

Appendix 3—Supporting Statement of Commissioner Brian Quintenz

I support today's proposal that would require designated contract markets (DCMs) to adopt rules that are reasonably designed to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading. It would also require DCMs to subject all electronic orders to pre-trade risk controls that are reasonably designed to prevent, detect and mitigate market disruptions and to provide prompt notice to the Commission in the event the platform experiences any significant disruptions. I believe all DCMs have already adopted regulations and pre-trade risk controls designed to address the risks posed by electronic trading. As I have noted previously, many—if not all—of the risks posed by electronic trading are already being effectively addressed through the market's incentive structure, including exchanges' and firms' own self-interest in implementing best practices. Therefore, today's proposal merely codifies the existing market practice of DCMs to have reasonable controls in place to mitigate electronic trading risks.

Significantly, the proposal puts forth a principles-based approach, allowing DCM trading and risk management controls to continue to evolve with the trading technology itself. As we have witnessed over the past decade, risk controls are constantly being updated and improved to respond to market developments. It is my view that these continuous enhancements are made possible because exchanges and firms have the flexibility and incentives to evolve and hold themselves to an ever-higher set of standards, rather than being held to a set of prescriptive regulatory requirements which can quickly become obsolete. By adopting a principles-based approach, the proposal would provide exchanges and market participants with the flexibility they need to innovate and evolve with technological developments. DCMs are well-positioned to determine and implement the rules and risk controls most effective for their markets. Under the proposed rule, DCMs would be required to adopt and implement rules and risk controls that are objectively reasonable. The Commission would monitor DCMs for compliance and take action if it determines that the DCM's rules and risk controls are objectively unreasonable.

The Technology Advisory Committee (TAC), which I am honored to sponsor, has explored the risks posed by electronic trading at length. In each of those discussions, it has become obvious that both DCMs and market participants take the risks of electronic trading seriously and have expended enormous effort and resources to address those risks.

For example, at one TAC meeting, we heard how the CME Group has implemented trading and volatility controls that complement, and in some cases exceed, eight recommendations published by the International Organization of Securities Commissions (IOSCO) regarding practices to manage volatility and preserve orderly trading. We also heard from the Futures Industry Association (FIA) about current best practices for electronic trading risk controls. FIA reported that through its surveys of exchanges, clearing firms, and trading firms, it has found widespread adoption of market integrity controls since 2010, including price banding and exchange market halts. FIA also previewed some of the next generation controls and best practices currently being developed by exchanges and firms to further refine and improve electronic trading systems. The Intercontinental Exchange (ICE) also presented on the risk controls ICE currently implements across all of its exchanges, noting how its implementation of controls was fully consistent with FIA's best practices. These presentations emphasize how critical it is for the Commission to adopt a principles-based approach that enables best practices to evolve over time. I believe the proposal issued today adopts such an approach and provides DCMs with the flexibility to continually improve their risk controls in response to technological and market advancements. I look forward to comment on the proposal.

It is also long overdue for the Commission to withdraw the Regulation Automated Trading Proposal and Supplemental Proposal (Regulation AT NPRMs). The Regulation AT NPRMs would have required certain types of market participants, based purely on their trading functionality, strategies or market access methods, to register with the Commission, notwithstanding that they did not act as intermediaries in the markets or hold customer funds. Moreover, the NPRMs proposed extremely prescriptive requirements for the types of risk controls that exchanges, futures commission merchants, and trading firms would be required to implement. Lastly, by withdrawing these NPRMs, the market and public can finally consider as dead the prior Commission's significant, and likely unconstitutional, overreach on accessing firms' proprietary source code and protected intellectual property without a subpoena.

In my view, the Regulation AT NPRMs were poorly crafted and flawed public policy that failed to understand the true risks of the electronic trading environment and the intrinsic incentives that exchanges and market participants have to mitigate and address those risks. I am pleased the Commission is officially rejecting the policy rationales and regulatory requirements proposed in the Regulation AT NPRMs and is instead embracing the principles-based approach of today's proposal.

Appendix 4—Statement of Dissent of Commissioner Rostin Behnam

I strongly support thoughtful and *meaningful* policy that addresses the use of automated systems in our markets.[1] As Chris Clearfield of System Logic, a research and consulting firm focusing on issues of risk and complexity remarked, ''In every situation, a trader or a piece of technology might fail, or a shock might trigger a liquidity event. What's important is that structures are in place to limit—not amplify—the impact on the overall system.'' [2] Any rule that we put forward should both minimize the potential for market disruptions and other operational problems that may arise from the automation of order origination, transmission or execution, and create structures to absorb and buffer breakdowns when they occur. Unfortunately, today's proposal regarding Electronic Trading Risk Principles does not meaningfully achieve this, and thus I respectfully dissent.

A little over ten years ago, on May 6, 2010, the Flash Crash shook our markets.[3] The prices of many U.S.-based equity products, including stock index futures, experienced an extraordinarily rapid decline and recovery. After this event, the staffs of the U.S. Securities and Exchange Commission (''SEC'') and CFTC issued a report to the Joint CFTC–SEC Advisory Committee on Emerging Regulatory Issues.[4] The report noted that ''[o]ne key lesson is that under stressed market conditions, the automated execution of a large sell order can trigger extreme price movements, especially if the automated execution algorithm does not take prices into account. Moreover, the interaction between automated execution programs and algorithmic trading strategies can quickly

[10] Tarbert, at 11–17.

[11] Di Lampedusa, at 22.

[1] The Commission's Office of the Chief Economist has found that over 96 percent of all on-exchange futures trading occurred on DCMs' electronic trading platforms. Haynes, Richard & Roberts, John S., ''Automated Trading in Futures Markets—Update #2'' at 8 (Mar. 26, 2019), available at *https://www.cftc.gov/sites/default/files/2019-04/ATS_2yr_Update_Final_2018_ada.pdf.*

[2] Chris Clearfield, *Vision Zero for Our Markets,* The Risk Desk, Dec. 21, 2016, at 4.

[3] *See* Findings Regarding the Market Events of May 6, 2010, Report of the Staffs of the CFTC and SEF to the Joint Advisory Committee on Emerging Regulatory Issues (Sept. 30, 2010), available at *http://www.cftc.gov/ucm/groups/public/@otherif/documents/ifdocs/staff-findings050610.pdf.*

[4] *Id.*

erode liquidity and result in disorderly markets.'' [5] In 2012, Knight Capital, a securities trading firm, suffered losses of more than $460 million due to a trading software coding error.[6] Other volatility events related to automated trading have followed with increasing regularity.[7]

After the Flash Crash, the CFTC initially worked with the SEC to establish controls to minimize the risk of automated trading disruptions. Knight Capital demonstrated that the Flash Crash was not a one-off event, and in 2013 the Commission published an extensive Concept Release on Risk Controls and System Safeguards for Automated Trading Environments (''Concept Release'').[8] Following public comments on the Concept Release, the Commission published ''Regulation AT,'' which proposed a series of risk controls, transparency measures, and other safeguards to address risks arising from automated trading on designated contract markets or ''DCMs.'' [9] Reg AT proposed pre-trade risk controls at three levels in the life-cycle of an order executed on a DCM: (i) Certain trading firms; (ii) futures commission merchants (''FCMs''); and (iii) DCMs. In 2016, again based on public comments, the Commission issued a supplemental notice of proposed rulemaking for Reg AT, proposing a revised framework with controls at two levels (instead of three levels initially proposed): (1) The AT Person or the FCM; and (2) the DCM.[10]

Since 2016, the Commission has not advanced policy designed to prevent or restrain the impact of these market disruptions resulting from automated trading. While the Commission has not acted, these events have continued to occur. In September and October 2019, the Eurodollar futures market experienced a significant increase in messaging.[11] According to reports, the volume of data generated by activity in Eurodollar futures increased tenfold.[12] The DCM responded by changing its rules to increase penalties for exceeding certain messaging thresholds and cutting off connections for repeat violators.[13] The DCM acted appropriately in such a situation and strengthened the rules for its participants; however, Commission policy could well have prevented this event by requiring pre-trade risk controls, including messaging thresholds.

Given the importance of the issue, I would like to commend the Chairman for stepping forward with a proposal today. However, as I considered this proposal, I found myself questioning what the proposed Risk Principles do differently than the status quo. The preamble seems to go to great lengths to make it clear that the Commission is not asking DCMs to do anything. The preamble states that the ''Commission believes that DCMs are addressing most, if not all, of the electronic trading risks currently presented to their trading platforms.'' [14] As the preamble discusses each of the three ''new'' Risk Principles, it goes on to describe all of the actions taken by DCMs today that meet the principles. The fact that the Commission is not asking DCMs to do anything new is clearest in the cost benefit analysis, which states that ''DCMs' current risk management practices, particularly those implemented to comply with existing regulations 38.157, 38.251(c), 38.255, and 38.607, already may comply with the requirements of proposed rules 38.251(e) through 38.251(g).'' [15] If the appropriate structures are in place, and we have dutifully conducted our DCM rule enforcement reviews and have found neither deficiencies nor areas for improvement, then is the exercise before us today anything more than creating a box to check? The only potentially new aspect of this proposal is that the preamble suggests different application in the future, as circumstances change. The Commission seems to want it both ways: we want to reassure DCMs that what they do now is enough, but at the same time the new risk principles potentially provide a blank check for the Commission to apply them differently in the future. Or perhaps, viewed differently, when there is a technology failure—and there will be—will the Commission stand by its principles or will it fashion an enforcement action around a black swan event so that everyone walks away bruised, but not harmed?

For market participants, this may be extremely confusing. What precisely are DCMs being asked to do, and what will they be asked to do in the future? Frankly, I am not sure. But it could be more than they bargained for.

The first Risk Principle requires DCMs to ''[a]dopt and implement rules . . . to prevent, detect, and mitigate market disruptions or system anomalies associated with electronic trading.'' None of the key terms in this principle are defined in the regulation or the preamble. DCMs are left some clues, but they are not told precisely what a market disruption or system anomaly is. Perhaps most importantly, they are not told what it means for something to be ''reasonably designed'' to prevent these things. This lack of clarity continues through the other two new Risk Principles. And while the Commission provides some clues by stating that current practice ''may'' meet the new principles, it then goes on to say that future circumstances may require future action by DCMs in order to comply with the principles.

As a recent article by our Chairman in the Harvard Business Law Review points out, the CFTC has a long tradition of principles-based regulation.[16] The concept runs through our core principles, which form the framework for much of what we do and how we regulate. It certainly is tempting to promulgate broad rules that provide the CFTC with flexibility to react to changes in the marketplace. The problem is that this flexibility comes at a number of costs—it potentially denies market participants the certainty they need to make business decisions, and, if the principles are too flexible, it denies market participants the notice and opportunity to comment that is required by the Administrative Procedures Act. These costs become too high where, as today, we promulgate rules that are too broad in their terms and too vague in application. There is a reason why the core principles for swap execution facilities (''SEFs, DCMs, and derivatives clearing organizations (''DCOs'') in our rule set are extensive, and why the regulations include appendices explaining Commission interpretation and acceptable practices. Without sufficient clarity, principles actually can become a vehicle for government overreach—a blank check for broad government action—and that includes enforcement action.

There is a saying in basketball that a good zone defense looks a lot like a man-to-man defense, and a good man-to-man defense looks a lot like a zone defense. I think the same can be said of principles-based regulation and rules-based regulation. Good principles-based regulation should look a lot like rules-based regulation—it should have enough clarity to provide market participants with certainty and the opportunity to provide comment regarding what regulation will look like.

It is worth noting that the Commission described the unanimously approved Reg AT proposal as principles-based.[17] Multiple commenters to that proposal noted that it was too principles-based.[18] I suspect that each of us on the Commission believes that the CFTC has a tradition of principles-based regulation, and that that tradition should continue. However, I think there is disagreement as to precisely what that means.[19]

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[5] *Id.* at 6.

[6] *See* SEC Press Release No. 2013–222, ''SEC Charges Knight Capital With Violations of Market Access Rule'' (Oct. 16, 2013), available at *http://www.sec.gov/News/PressRelease/Detail/PressRelease/1370539879795.*

[7] For a list of volatility events between 2014 and 2017, *see* the International Organization of Securities Commissions (''IOSCO'') March 2018 Consultant Report on Mechanisms Used by Trading Venues to Manage Extreme Volatility and Preserve Orderly Trading (''IOSCO Report''), at 3, available at *https://www.iosco.org/library/pubdocs/pdf/IOSCOPD607.pdf.*

[8] Concept Release on Risk Controls and System Safeguards for Automated Trading Environments, 78 FR 56542 (Sept. 12, 2013).

[9] Regulation Automated Trading, Proposed Rule, 80 FR 78824 (Dec. 17, 2015).

[10] Supplemental Regulation AT NPRM, 81 FR 85334 (Nov. 25, 2016).

[11] *See* Osipovich, Alexander, ''Futures Exchange Reins in Runaway Trading Algorithms,'' *Wall Street Journal* (Oct. 29, 2019), available at *https://www.wsj.com/articles/futures-exchange-reins-in-runaway-trading-algorithms-11572377375.*

[12] *Id.*

[13] *See* CME Group Globex Messaging Efficiency Program, available at *https://www.cmegroup.com/globex/trade-on-cme-globex/messaging-efficiency-program.html.*

[14] Proposal at I.A.

[15] Proposal at IV.C.3.

[16] Press Release Number 8183–20, CFTC, ICYMI: Harvard Business Law Review Publishes Chairman Tarbert's Framework for Sound Regulation (June 15, 2020), *https://www.cftc.gov/PressRoom/PressReleases/8183-20.*

[17] Reg AT at 78838.

[18] *See* Comments of Americans For Financial Reform and Better Markets, Inc., available at *https://comments.cftc.gov/PublicComments/CommentList.aspx?id=1762.*

[19] As I have stated before, ''A principles-based approach provides greater flexibility, but more importantly focuses on thoughtful consideration, evaluation, and adoption of policies, procedures, and practices as opposed to checking the box on a

Finally, I want to make a few comments on the vote regarding the withdrawal of Reg AT. On one hand, the Risk Principles proposal today expressly is not about automated or algorithmic trading. This applies to electronic trading generally. Yet there seems to be a perception that this is a replacement for Reg AT, and that is already reflected in media accounts of our action today.[20] And if there is any question, the Commission is separately voting on withdrawal of Reg AT (and mentions Reg AT repeatedly in the document) at the same time it is issuing this NPRM.

A separate vote specifically to withdraw a prior Commission proposal is highly unusual—particularly in a situation where, as here, the original proposal was unanimously issued. I believe that this action establishes a dangerous precedent for a Commission that has historically prided itself on its collegiality and efforts to work in a bipartisan fashion. I have followed in a tradition of some of my predecessors on the Commission, at times voting for proposals that I would not have supported as final rules, for the purpose of advancing the conversation.[21] I worry that the withdrawal of Reg AT could lead to future withdrawals of Commission proposals, and a loss of this historical collegiality. We should be standing on the shoulders of those who came before us, not tearing down what came before us.

Market participants expressed valid concerns to the original Reg AT, as they do with many of our proposals. But, market displeasure with just one or even a few of those original policy concepts is not a reason to throw away the rest of the proposal. Let's revisit, review, and refresh sound policy to better reflect modern market structure and a healthy relationship between market participant and market regulator. I firmly believe we collectively strive for the same goal: Safe, transparent, orderly, and fair markets. Unfortunately, today's proposal does not advance the conversation, and as such I cannot support it.

The preamble to today's NPRM expressly says ''The Risk Principles proposed here are intended to accomplish a similar goal . . .'' to the original Reg AT.[22] The Reg AT proposal rule text took up more than 6 pages in the **Federal Register**, and made revisions and additions to Parts 1, 39, 40, and 170, providing a comprehensive—and principles-based—framework for addressing a very real issue that all market participants should be concerned about. Today's proposed principles are all of three sentences long. This is not a miracle of brevity. It just shows that the proposal today does not really do anything—while paradoxically writing the Commission a blank check to change its mind about what the principles mean in the future and who will stand by them when the next black swan lands.

Appendix 5—Statement of Commissioner Dan M. Berkovitz

I support issuing for public comment the proposed rule on Electronic Trading Risk Principles (''Proposed Rule''). The Proposed Rule is a limited step to address potential market disruptions arising from system errors or malfunctions in electronic trading. Although it leaves important issues unaddressed, the Proposed Rule recognizes the need to update the Commission's regulations to keep pace with the speed, interconnection, and automation of modern markets. I support the Commission's long-overdue re-engagement in this area.

While I support issuing the Proposed Rule for public comment, I do not support withdrawing the proposed rule known as Regulation Automated Trading (''Reg AT'').[1] The notice of withdrawal reflects a belief that there is nothing of value in Reg AT. That is simply not true. Reg AT was a comprehensive approach for addressing automated trading in Commission regulated markets. Certain elements of Reg AT attracted intense opposition and may have been a bridge too far. However, I applaud that proposal's efforts to identify the sources of risk and implement meaningful risk controls. I believe the comments received on Reg AT are worth evaluating going forward.

The Proposed Rule would codify in part 38 of the Commission's regulations three ''Risk Principles'' applicable to electronic trading on designated contract markets (''DCMs''). Risk Principle 1, for example, would require DCMs to implement rules applicable to market participants to prevent, detect, and mitigate market disruptions and system anomalies. Risk Principle 2 would also require DCMs to implement their own pre-trade risk controls. While worthwhile as statements of principle, these proposed requirements are drafted in terms that may ultimately prove too high-level to achieve the goal of effectively preventing, detecting, and mitigating market disruptions and system anomalies. This concern is discussed in greater detail below, and I look forward to public comment on the issue.

The Proposed Rule includes Acceptable Practices in Appendix B to part 38, which provide that a DCM can comply with the Risk Principles through rules and risk controls that are ''reasonably designed'' to prevent, detect, and mitigate market disruptions and system anomalies. The Proposed Rule specifies that reasonableness is an objective measure, and that a DCM rule or risk control that is not ''reasonably designed'' would not satisfy the Acceptable Practices or the Risk Principles. As the Proposed Rule indicates, the Commission will monitor DCMs' compliance with the Risk Principles. In this regard, the Commission has multiple oversight activities at its disposal, including market surveillance activities, reviews of new rule certifications and approval requests, and rule enforcement reviews.

The Proposed Rule is also clear on the fundamental division of authority under the Commodity Exchange Act (''CEA'') between DCMs and the Commission. Amendments to the CEA made through the Commodity Futures Modernization Act (''CFMA'') in the year 2000 introduced the core principle regime and provided DCMs with flexibility in establishing how they comply with a core principle.[2] Ten years later, however, learning from the 2008 financial crisis and the excesses of deregulation, the Dodd-Frank Act overhauled the CEA, including in its treatment of the core principle regime.[3] Specifically, section 735 of the Dodd-Frank Act made clear that a DCM's discretion with respect to core principle compliance was circumscribed by any rule or regulation that the Commission might adopt pursuant to a core principle.[4] I am able to support today's Proposed Rule for publication in the **Federal Register** because of improvements that clarify the respective authorities between a DCM and the Commission. Under the CEA, the Commission is the ultimate arbiter of whether a DCM's rules and risk controls are reasonably designed, under an objective standard. I thank the Chairman for his efforts at building consensus in this regard.

The Proposed Rule overlaps with existing requirements in part 38 of the Commission regulations, including regulation 38.255, which requires DCMs to ''establish and maintain risk control mechanisms to prevent and reduce the potential risk of price distortions and market disruptions . . . .'' [5] While the Proposed Rule and Risk Principle 2 are more explicit with respect to electronic trading, they may add little to existing requirements and practices regarding the risk controls that DCMs build into their own systems. Indeed, the Proposed Rule provides numerous examples of specific risk controls at major DCMs that likely already meet this requirement, and of disciplinary actions taken by DCMs against market participants related to electronic trading. Although the Commission articulates a need for updating its risk control requirements, the fact that the Risk Principles as proposed are likely to have no practical effect undermines the usefulness of this exercise.

The Proposed Rule possibly may be of greater benefit in with respect to Risk Principle 1 and its requirement that DCMs

predetermined, one-size-fits-all outcome. However, the best principles-based rules in the world will not succeed absent: (1) Clear guidance from regulators; (2) adequate means to measure and ensure compliance; and (3) willingness to enforce compliance and punish those who fail to ensure compliance with the rules.'' *See* Rostin Behnam, Commissioner, CFTC, Remarks of Commissioner Rostin Behnam before the FIA/SIFMA Asset Management Group, Asset Management Derivatives Forum 2018, Dana Point, California (Feb. 8, 2018), *https://www.cftc.gov/PressRoom/Speeches Testimony/opabehnam2.*

[20] *See* Bain, Ben, ''Flash Boys New Rules Won't Make Them Hand Over Trading Secrets,'' Bloomberg (Jun. 18, 2020), *https://www.bloomberg.com/news/articles/2020-06-18/flash-boys-new-rules-won-t-make-them-hand-over-trading-secrets.*

[21] *See* Concurring Statement of Commissioner Rostin Behnam Regarding Swap Execution Facilities and Trade Execution Requirement, (Nov. 5, 2018). *https://www.cftc.gov/PressRoom/Speeches Testimony/behnamstatement110518a.*

[22] Proposal at I.B.

[1] Regulation Automated Trading, 80 FR 78824 (Dec. 17, 2015); 81 FR 85334 (Nov. 25, 2016) (supplemental notice of proposed rulemaking for Regulation Automated Trading).

[2] Commodity Futures Modernization Act of 2000, Public Law 106–554, 114 Stat. 2763A–365 (2000).

[3] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[4] Commodity Exchange Act section 5(d)(1)(B), 7 U.S.C. 7(d)(1)(B) (2010).

[5] 17 CFR 38.255 (2012).

implement risk control rules applicable to their market participants. Market participants, who originate orders via systems ranging from comparatively simple automated order routers to nearly autonomous algorithmic trading systems, are crucial focal points for any adequate system of risk controls. An effective system of risk controls must therefore include controls at multiple stages in the life cycle of an automated order submitted to an electronic trade matching engine. Although Risk Principle 1 could benefit from greater rigor, it is nonetheless a critical recognition that market participants have an important role in any effective risk control framework.

I look forward to public comments on additional measures that the Commission should consider for effective risk controls across the ecosystem of electronic and algorithmic trading. My support for any final rule that may arise from this proposal is conditioned upon a thorough articulation of the technology-driven risks present in today's markets, and a concomitant regulatory response that will meaningfully address such risks. In a market environment where the vast majority of trading is now electronic and automated, inaction is a luxury that we can ill-afford.

Although the Proposed Rule may be characterized as a ''principles-based'' approach, in fact the Risk Principles are not a new approach to the regulation of risks from electronic trading. The current regulation establishing requirements on DCMs to impose risk controls—Regulation 38.255—is principles-based. Regulation 38.255 states: ''The designated contract market must establish and maintain risk control mechanisms to prevent and reduce the potential risk of price distortions and market disruptions, including, but not limited to, market restrictions that pause or halt trading in market conditions prescribed by the designated contract market.'' One might ask, therefore, why do we need another principles-based regulation when we already have a principles-based regulation? The preamble to the Proposed Rule notes the ''overlap'' between Regulation 38.255 and the proposed Risk Principles, and states ''it is beneficial to provide further clarity to DCMs about their obligations to address certain situations associated with electronic trading.'' In other words, the principles-based regulations previously adopted by the Commission *are not prescriptive enough* to address the risks currently posed by electronic trading. I fully agree. Although I am voting today to put out this proposal for public comment, I am not yet convinced—and I look forward to public comment on whether—the principles-based regulations proposed today are in fact sufficiently detailed or comprehensive to effectively address those risks.

I thank the staff of the Division of Market Oversight for their work on the Proposed Rule and for their patience as the Commission worked through multiple iterations of this proposal. I also thank the Chairman for his engagement and effort to build consensus. I believe that the Proposed Rule is a much better regulatory outcome because of the extensive dialogue and give-and-take that led to the rule before us today.

[FR Doc. 2020–14381 Filed 7–14–20; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–130081–19]

RIN 1545–BP67

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB89

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9923–P]

RIN 0938–AT49

Grandfathered Group Health Plans and Grandfathered Group Health Insurance Coverage

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document is a notice of proposed rulemaking regarding grandfathered group health plans and grandfathered group health insurance coverage that would, if finalized, amend current rules to provide greater flexibility for certain grandfathered health plans to make changes to certain types of cost-sharing requirements without causing a loss of grandfather status.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 14, 2020.

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Departments. Please do not submit duplicates.

All comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, refer to file code RIN 1210–AB89. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, U.S. Department of Labor, Attention: RIN 1210–AB89, 200 Constitution Avenue NW, Room N–5653, Washington, DC 20210.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, U.S. Department of Labor, Attention: RIN 1210–AB89, 200 Constitution Avenue NW, Room N–5653, Washington, DC 20210.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: William Fischer, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

David Sydlik or Frank Kolb, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335.

Cam Clemmons, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (301) 492–4400.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the DOL's website (*www.dol.gov/ebsa*). In addition, information from the Department of

Health and Human Services (HHS) on private health insurance coverage and on non-federal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received before the close of the comment period are posted on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

A. Purpose

On January 20, 2017, the President issued Executive Order 13765, ''Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal'' (82 FR 8351) ''to minimize the unwarranted economic and regulatory burdens of the [Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, PPACA), as amended].'' To meet these objectives, the President directed that the executive departments and agencies with authorities and responsibilities under PPACA, ''to the maximum extent permitted by law . . . shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of [PPACA] that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.''

The Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Departments) share interpretive jurisdiction over section 1251 of PPACA, which generally provides that certain group health plans and health insurance coverage existing as of March 23, 2010, the date of enactment of PPACA (referred to collectively in the statute as grandfathered health plans), are subject to only certain provisions of PPACA. Consistent with the objectives of Executive Order 13765, on February 25, 2019, the Departments issued a request for information regarding grandfathered group health plans and grandfathered group health insurance coverage (2019 RFI).[1] The purpose of the 2019 RFI was to gather input from the public in order to better understand the challenges that group health plans and group health insurance issuers face in avoiding a loss of grandfather status, and to determine whether there are opportunities for the Departments to assist such plans and issuers, consistent with the law, in preserving the grandfather status of group health plans and group health insurance coverage in ways that would benefit plan participants and beneficiaries, employers, employee organizations, and other stakeholders.

Based on feedback received from stakeholders who submitted comments in response to the 2019 RFI, the Departments are issuing this notice of proposed rulemaking that would, if finalized, amend current rules to provide greater flexibility for certain grandfathered health plans to make changes to certain types of cost-sharing requirements without causing a loss of grandfather status. In the Departments' view, these proposed amendments are appropriate because they would enable these plans to continue offering affordable coverage while also enhancing their ability to respond to rising healthcare costs. In some cases, the proposed amendments would also ensure that the plans are able to comply with minimum cost-sharing requirements for high deductible health plans (HDHPs) so enrolled individuals are eligible to contribute to health savings accounts (HSAs).

These proposed rules would only address the requirements for grandfathered group health plans and grandfathered group health insurance coverage, and would not apply to or otherwise change the current requirements applicable to grandfathered individual health insurance coverage. With respect to individual health insurance coverage, it is the Departments' understanding that the number of individuals with grandfathered individual health insurance coverage has declined each year since PPACA was enacted. As one commenter noted, this decline in enrollment in grandfathered individual health insurance coverage will continue due to the natural churn that occurs, because most consumers stay in the individual market for less than five years.[2] Compared to the number of individuals in grandfathered group health plans and group health insurance coverage, only a small number of individuals are enrolled in grandfathered individual health insurance coverage.[3] The Departments are therefore of the view that any amendments to requirements for grandfathered individual health insurance coverage would be of limited utility.

B. Grandfathered Group Health Plans and Grandfathered Group Health Insurance Coverage

Section 1251 of PPACA provides that grandfathered health plans are subject to certain, but not all, provisions of PPACA for as long as they maintain their status as grandfathered health plans.[4] For example, grandfathered health plans are subject neither to the requirement to cover certain preventive services without cost sharing under section 2713 of the Public Health Service Act (PHS Act), enacted by section 1001 of PPACA, nor to the annual limitation on cost sharing set forth under section 1302(c) of PPACA and section 2707(b) of the PHS Act, enacted by section 1201 of PPACA. If a plan were to lose its grandfather status, it would be required to comply with both provisions, in addition to several other requirements.

On June 17, 2010, the Departments issued interim final rules with request for comments implementing section 1251 of PPACA.[5] On November 17, 2010, the Departments issued an amendment to the interim final rules with request for comments to permit certain changes in policies, certificates,

[1] 84 FR 5969 (Feb. 25, 2019).

[2] The cause of this churn varies. For example, beginning a new job that offers group health insurance coverage may result in the natural transition from the individual market to the group market. Eligibility for Medicaid or Medicare can also result in a consumer leaving the individual market.

[3] HHS estimates that less than seven percent of enrollees in grandfathered plans have individual market coverage. This estimate is based on analysis of enrollment data issuers submitted in the HHS Health Insurance and Oversight System (HIOS) and the CMS External Data Gathering Environment (EDGE) for the 2018 plan year, as well as Kaiser Family Foundation estimates regarding the percentage of enrollees with employer-sponsored coverage that are covered by a grandfathered health plan.

[4] For a list of the market reform provisions applicable to grandfathered health plans under title XXVII of the PHS Act that PPACA added or amended and were incorporated into the Employee Retirement Income Security Act of 1974 (ERISA) and the Internal Revenue Code of 1986 (the Code), visit *https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/grandfathered-health-plans-provisions-summary-chart.pdf.*

[5] 75 FR 34538 (June 17, 2010).

or contracts of insurance without a loss of grandfather status.[6] Also, over the course of 2010 and 2011, the Departments released Affordable Care Act Implementation Frequently Asked Questions (FAQs) Parts I, II, IV, V, and VI to answer questions related to maintaining a plan's status as a grandfathered health plan.[7] After consideration of the comments and feedback received from stakeholders, the Departments issued regulations on November 18, 2015, which finalized the interim final rules without substantial change and incorporated the clarifications that the Departments had previously provided in other guidance (2015 final rules).[8]

In general, under the 2015 final rules, a group health plan or group health insurance coverage is considered grandfathered if it has continuously provided coverage for someone (not necessarily the same person, but at all times at least one person) since March 23, 2010, and if the plan (or its sponsor) or issuer has not taken certain actions.

Under the 2015 final rules, certain changes to a group health plan or coverage do not result in a loss of grandfather status. For example, new employees and their families may enroll in a group health plan or group health insurance coverage without causing a loss of grandfather status. Further, the addition of a new contributing employer or a new group of employees of an existing contributing employer to a grandfathered multiemployer health plan will not affect the plan's grandfather status. Also, grandfather status is determined separately for each benefit package under a group health plan or coverage; thus, if any benefit package under the plan or coverage loses its grandfather status, it will not affect the grandfather status of the other benefit packages.

The 2015 final rules specify when changes to the terms of a plan or coverage cause the plan or coverage to cease to be a grandfathered health plan. Specifically, the regulations outline certain changes to benefits, cost-sharing requirements, and contribution rates that will cause a plan or coverage to relinquish its grandfather status. There are six types of changes (measured from March 23, 2010) that will cause a group health plan or health insurance coverage to cease to be grandfathered:

1. The elimination of all or substantially all benefits to diagnose or treat a particular condition;

2. Any increase in a percentage cost-sharing requirement (such as coinsurance);

3. Any increase in a fixed-amount cost-sharing requirement (other than a copayment) (such as a deductible or out-of-pocket maximum) that exceeds certain thresholds;

4. Any increase in a fixed-amount copayment that exceeds certain thresholds;

5. A decrease in contribution rate by an employer or employee organization toward the cost of coverage by more than five percentage points below the contribution rate for the coverage period that includes March 23, 2010; or

6. The imposition of annual limits on the dollar value of all benefits for group health plans and insurance coverage that did not impose such a limit prior to March 23, 2010.

The 2015 final rules provide different thresholds for the increases to different types of cost-sharing requirements that will cause a loss of grandfather status. The nominal dollar amount of a coinsurance obligation automatically rises when the cost of the healthcare benefit subject to the coinsurance obligation increases, so changes to the level of coinsurance (such as modifying a requirement that the patient pay 20 percent to a requirement that the patient pay 30 percent of inpatient surgery costs) could significantly alter the financial obligation of consumers and a plan or health insurance coverage. On the other hand, fixed-amount cost-sharing requirements (such as copayments and deductibles) do not automatically rise when healthcare costs increase. This means that changes to fixed-amount cost-sharing requirements (for example, modifying a $35 copayment to a $40 copayment for outpatient doctor visits) may be reasonable to keep pace with the rising cost of medical items and services. Accordingly, under the 2015 final rules, any increase in a percentage cost-sharing requirement (such as coinsurance) causes a plan or health insurance coverage to cease to be a grandfathered health plan. With respect to fixed-amount cost-sharing requirements, however, there are two standards for permitted increases, one for fixed-amount cost-sharing requirements other than copayments (for example, deductibles and out-of-pocket maximums) and another for copayments.

With respect to fixed-amount cost-sharing requirements other than copayments, a plan or coverage ceases to be a grandfathered health plan if there is an increase, since March 23, 2010, that is greater than the maximum percentage increase. For fixed-amount copayments, a plan or coverage ceases to be a grandfathered health plan if there is an increase, since March 23, 2010, in the copayment that exceeds the greater of (1) the maximum percentage increase or (2) five dollars increased by medical inflation. The 2015 final rules define the maximum percentage increase as medical inflation (from March 23, 2010) plus 15 percentage points. For this purpose, medical inflation is defined by reference to the overall medical care component of the Consumer Price Index for All Urban Consumers, unadjusted (CPI–U), published by the Department of Labor using the 1982–1984 base of 100.

For any change that causes a loss of grandfather status under the 2015 final rules, the plan or coverage will cease to be a grandfathered plan when the change becomes effective, regardless of when the change is adopted.

In addition, the 2015 final rules require that a grandfathered plan or coverage include a statement in any summary of benefits provided under the plan that it believes the plan or coverage is a grandfathered health plan, as well as provide contact information for questions and complaints. Failure to provide this disclosure results in a loss of grandfather status. The 2015 final rules further provide that, once grandfather status is relinquished, there is no opportunity to regain it.

C. 2019 Request for Information

It is the Departments' understanding that the number of grandfathered group health plans and group health insurance policies has declined each year since the enactment of PPACA, but many employers continue to maintain grandfathered group health plans and coverage. The fact that a significant

[6] 75 FR 70114 (Nov. 17, 2010).

[7] *See* Affordable Care Act Implementation FAQs Part I, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-i.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html;* Affordable Care Act Implementation FAQs Part II, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-ii.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html;* Affordable Care Act Implementation FAQs Part IV, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-iv.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html;* Affordable Care Act Implementation FAQs Part V, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-v.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html;* and Affordable Care Act Implementation FAQs Part VI, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-vi.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html.*

[8] 80 FR 72192 (Nov. 18, 2015), codified at 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140.

number of grandfathered group health plans and coverage remain indicates that some employers and issuers have found value in preserving grandfather status. Accordingly, on February 25, 2019, the Departments published in the **Federal Register** the 2019 RFI [9] to gather input from the public in order to better understand the challenges that group health plans and group health insurance issuers face in avoiding a loss of grandfather status and to determine whether there are opportunities for the Departments to assist such plans and issuers, consistent with the law, in preserving the grandfather status of group health plans and group health insurance coverage in ways that would benefit plan participants and beneficiaries, employers, employee organizations, and other stakeholders.

Comments submitted in response to the 2019 RFI provided information regarding grandfathered health plans that has informed these proposed rules. Commenters shared data regarding the prevalence of grandfathered group health plans and grandfathered group health insurance coverage, insights regarding the impact that grandfathered plans have had in terms of delivering benefits to participants and beneficiaries at a lower cost than non-grandfathered plans, and suggestions for potential amendments to the Departments' 2015 final rules that would provide more flexibility for a plan or coverage to retain grandfather status.

Several commenters directed the Departments' attention to a Kaiser Family Foundation survey, which indicates that one out of every five firms that offered health benefits in 2018 offered at least one grandfathered health plan, and 16 percent of covered workers were enrolled in a grandfathered group health plan that year.[10] One commenter indicated the incidence of grandfathered plan status differs by various types of plan sponsors. Another commenter cited survey data released in 2018 by the International Foundation of Employee Benefit Plans, which indicated that 57 percent of multiemployer plans are grandfathered, compared to 20 percent of private-sector plans and 30 percent of public sector plans. However, a professional association with members who work with employer groups on health plan design and administration commented that their members have found far fewer grandfathered plans than survey results suggest are in existence and suggested that very large employers with self-funded plans may have a disproportionate share of grandfathered plans, as well as that some employers that have ''grandmothered'' plans or that previously had grandfathered plans may unintentionally be reporting incorrectly in surveys that they still have grandfathered plans.[11]

Some commenters stated that grandfathered health plans are less comprehensive and provide fewer consumer protections than non-grandfathered plans; thus, these commenters opined that the Departments should not amend the 2015 final rules to provide any greater flexibility for a plan or coverage to maintain grandfather status. Other commenters noted, however, that grandfathered plans often have lower premiums and cost-sharing requirements than non-grandfathered plans. One commenter gave examples of premium increases ranging from 10 percent to 40 percent that grandfathered plan participants would experience if they transitioned to non-grandfathered group health plans. Several commenters also argued that grandfathered health plans do in fact offer comprehensive benefits and in some cases are even more generous than certain non-grandfathered plans that are subject to all the requirements of PPACA. Some commenters also stated that they have found that their grandfathered plans offer more robust provider networks than other coverage options that are available to them or that they want to ensure that they are able to keep receiving care from current in-network providers.

Commenters who supported allowing greater flexibility for grandfathered health plans offered a range of suggestions on how the 2015 final rules should be amended. For example, several commenters requested additional flexibility regarding plan or coverage changes that would constitute an elimination of substantially all benefits to diagnose or treat a condition, arguing that it is often difficult to discern what constitutes a benefit reduction given that the regulations apply a ''facts and circumstances'' standard. Some commenters requested flexibility to make certain changes so long as the grandfathered plan or coverage's actuarial value is not affected. Some commenters also stated that the 2015 final rules should be amended to permit decreases in contribution rates by employers and employee organizations by more than five percentage points to account for employers experiencing a business change or economic downturn and the difficulty issuers face in gathering necessary information from employers to know that their contribution rates have not decreased.

Commenters also suggested amendments relating to the permitted changes in cost-sharing requirements for grandfathered health plans. These commenters generally argued that the 2015 final rules were too restrictive. Several commenters stated that relying on the medical care component of the CPI–U for purposes of those rules to account for inflation adjustments to the maximum percentage increase was misguided, and the methodology used to calculate the ''premium adjustment percentage'' (as defined in 45 CFR 156.130) would be more appropriate because it is tied to the increase in premiums for health insurance and, therefore, better reflects the increase in costs for health coverage. These commenters also noted that relying on the premium adjustment percentage would be consistent with the methodology used to adjust the annual limitation on cost sharing under section 1302(c) of PPACA and section 2707(b) of the PHS Act that applies to non-grandfathered plans. Additionally, one commenter articulated a concern that the 2015 final rules eventually may preclude some grandfathered group health plans or issuers of grandfathered

[9] 84 FR 5969 (Feb. 25, 2019), available at *https://www.federalregister.gov/documents/2019/02/25/2019-03170/request-for-information-regarding-grandfathered-group-health-plans-and-grandfathered-group-health.*

[10] On September 25, 2019, the Kaiser Family Foundation issued its 2019 report, which showed little change since 2018 with respect to grandfathered plans. According to survey data, 22 percent of offering firms report having at least one grandfathered plan in 2019, and 13 percent of covered workers were enrolled in a grandfathered health plan in 2019. *See 2019 Employer Health Benefits Survey,* Kaiser Family Foundation, available at *https://www.kff.org/health-costs/report/2019-employer-health-benefits-survey/. See also 2018 Employer Health Benefits Survey,* Kaiser Family Foundation, available at *https://www.kff.org/report-section/2018-employer-healthbenefits-survey-section-13-grandfathered-healthplans/.*

[11] ''Grandmothered'' plans, also known as transitional plans, are certain non-grandfathered health insurance coverage in the small group and individual market that meet certain conditions. On November 14, 2013, CMS issued a letter to the State Insurance Commissioners outlining a policy under which, if permitted by the state, non-grandfathered small group and individual market health plans that were in effect on October 1, 2013, would send a notice to all individuals and small businesses that received or would otherwise receive a cancellation or termination notice with respect to the coverage, and the coverage would not be treated as being out of compliance with certain specified market reforms. CMS has extended this non-enforcement policy each year, with the most recent extension in effect until policy years beginning on or before October 1, 2021, provided that all such coverage comes into compliance by January 1, 2022. *See Insurance Standards Bulletin Series—INFORMATION—Extension of Limited Non-Enforcement Policy through 2021* (January 31, 2020), available at *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2021.pdf.*

group health insurance coverage from being able to make changes to cost-sharing requirements that are necessary for a plan to maintain its status as an HDHP within the meaning of section 223 of the Internal Revenue Code (Code), which would effectively mean that individuals covered by those plans would no longer be eligible to contribute to an HSA.

D. The Premium Adjustment Percentage

Section 1302(c)(4) of PPACA directs the Secretary of HHS to determine an annual premium adjustment percentage, a measure of premium growth that is used to set the rate of increase for three parameters detailed in PPACA: (1) The maximum annual limitation on cost sharing (defined at 45 CFR 156.130(a)); (2) the required contribution percentage used to determine eligibility for certain exemptions under Code section 5000A (defined at 45 CFR 155.605(d)(2)); and (3) the employer shared responsibility payment amounts under Code section 4980H(a) and (b) (see Code section 4980H(c)(5)). Section 1302(c)(4) of PPACA and 45 CFR 156.130(e) provide that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and 45 CFR 156.130(e) provides that this percentage will be published in the annual HHS notice of benefit and payment parameters.

To calculate the premium adjustment percentage for a benefit year, HHS calculates the percentage by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds the average per capita premium for health insurance for 2013, and rounds the resulting percentage to 10 significant digits. The resulting premium index reflects cumulative, historic growth in premiums from 2013 through the preceding year. HHS calculates the premium adjustment percentage using as a premium growth measure the most recently available, at the time of proposal in the annual HHS notice of benefit and payment parameters proposed rule, National Health Expenditure Accounts (NHEA) projection of per enrollee premiums for private health insurance, excluding Medigap and property and casualty insurance, for 2013 and the preceding calendar year.[12]

[12] 85 FR 29164, 29228 (May 14, 2020). The series used in the determinations of the adjustment percentages can be found in Table 17 on the CMS website, which can be accessed by clicking the ''NHE Projections 2018–2027—Tables'' link located in the Downloads section at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.* A detailed description of the NHE projection methodology is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.*

E. High Deductible Health Plans and HSA-Compatibility

Section 223 of the Code permits eligible individuals to establish and contribute to HSAs. HSAs are tax-favored accounts established for the purpose of providing tax benefits to pay for qualified medical expenses on behalf of the account beneficiary, his or her spouse, and any dependents claimed. Among the requirements for an individual to qualify as an eligible individual under section 223(c)(1) of the Code (and thus to be eligible to make tax-favored contributions to an HSA) is the requirement that the individual be covered under an HDHP. An HDHP is a health plan that satisfies certain requirements with respect to minimum deductibles and maximum out-of-pocket expenses, which increase annually with cost-of-living adjustments. Generally, except for preventive care, an HDHP may not provide benefits for any year until the deductible for that year is met. Pursuant to section 223(g) of the Code, the minimum deductible for an HDHP is adjusted annually for cost-of-living based on changes in the CPI–U.

II. Overview of Proposed Rules

A. Introduction

This notice of proposed rulemaking would, if finalized, amend the 2015 final rules to provide greater flexibility for grandfathered group health plans and issuers of grandfathered group health insurance coverage to make certain changes without causing a loss of grandfather status. However, there is no authority for non-grandfathered plans to become grandfathered, and therefore these proposed rules would not provide any opportunity for a plan or coverage that has lost its grandfather status under the 2015 final rules to regain that status.

In issuing these proposed rules, the Departments considered comments submitted in response to the 2019 RFI regarding ways that the 2015 final rules should be amended. Many suggestions outlined in the comments are not being proposed here because, in the Departments' view, they would allow for such significant changes that the modified plan or coverage could not reasonably be described as being the same plan or coverage that was offered on March 23, 2010, for purposes of grandfather status. However, the commenters' arguments that there are better means of accounting for inflation in the standard for the maximum percentage increase that should be permitted to fixed-amount cost-sharing requirements were persuasive. The Departments also agree that, as one commenter highlighted, there is an opportunity to clarify that changes to fixed-amount cost-sharing requirements that are necessary for a plan to maintain its status as an HDHP should not cause a loss of grandfather status. Given that the 2015 final rules permit increases that are meant to account for inflation in healthcare costs over time, the Departments are of the view that these suggestions are reasonably narrow and consistent with the intent of the 2015 final rules to permit adjustments in response to inflation without causing a loss of grandfather status.

Accordingly, these proposed rules would amend the 2015 final rules in two ways. First, these proposed rules include a new paragraph (g)(3) which would specify that grandfathered group health plans and grandfathered group health insurance coverage that are HDHPs may make changes to fixed-amount cost-sharing requirements that would otherwise cause a loss of grandfather status without causing a loss of grandfather status, but only to the extent those changes are necessary to comply with the requirements for HDHPs under section 223(c)(2) of the Code. Second, these proposed rules include a revised definition of ''maximum percentage increase'' in redesignated paragraph (g)(4), which provides an alternative method of determining that amount based on the premium adjustment percentage. This alternative method would be available only for grandfathered group health plans and grandfathered group health insurance coverage with changes that are effective on or after the effective date of a final rule.

The Departments request comments on all aspects of these proposed rules. In the preamble discussion that follows, the Departments also solicit comments on specific issues related to the proposed rules where stakeholder feedback would be particularly useful in evaluating whether and how to issue final rules.

B. Special Rule for Certain Grandfathered HDHPs

As explained above, paragraph (g)(1) of the 2015 final rules identifies certain types of changes that will cause a plan or coverage to cease to be a grandfathered health plan, including

increases in cost-sharing requirements that exceed certain thresholds. However, cost-sharing requirements for a grandfathered group health plan or group health insurance coverage that is an HDHP must satisfy the minimum annual deductible requirement and maximum out-of-pocket expenses requirement under section 223(c)(2)(A) of the Code. These amounts are updated annually to reflect a cost-of-living adjustment and are published each year by the Internal Revenue Service.

The annual cost-of-living adjustment to the required minimum deductible for an HDHP has not yet exceeded the maximum percentage increase that would cause an HDHP to lose grandfather status.[13] Nevertheless, the Departments are of the view that there is value in providing assurance to grandfathered plans that if a grandfathered group health plan or group health insurance coverage that is an HDHP increases its fixed-amount cost-sharing requirements to meet a future adjusted minimum annual deductible requirement under section 223(c)(2)(A) of the Code that is greater than the increase that would be permitted under paragraph (g)(1), such an increase would not cause the plan or coverage to relinquish its grandfather status. Otherwise, if such a conflict were to occur, the sponsor of the plan would have to decide whether to preserve the plan's grandfather status or its status as an HDHP. This would mean participants and beneficiaries would experience either substantial changes to their coverage (and likely premium increases) or a loss of eligibility to contribute to an HSA.

To address this potential conflict, these proposed rules include a new paragraph (g)(3), which provides that, with respect to a grandfathered group health plan or group health insurance coverage that is an HDHP, increases to fixed-amount cost-sharing requirements that otherwise would cause a loss of grandfather status would not cause the plan or coverage to relinquish its grandfather status, but only to the extent the increases are necessary to maintain its status as an HDHP under section 223(c)(2)(A) of the Code.[14] Thus, increases with respect to such a plan or coverage that would otherwise cause a loss of grandfather status and that exceed the amount necessary to satisfy the minimum annual deductible requirement under section 223(c)(2)(A) of the Code would still cause a loss of grandfather status. These proposed rules would also add a new example 11 under paragraph (g)(5) to illustrate how this special rule would apply.

C. Definition of Maximum Percentage Increase

The Departments agree with stakeholders who submitted comments on the 2019 RFI stating that the premium adjustment percentage (as defined at 45 CFR 156.130(e) and published for each year by HHS in the annual notice of benefit and payment parameters) may be a more appropriate measurement of changes in healthcare costs over time than medical inflation, as defined in the 2015 final rules.

Under the 2015 final rules, medical inflation means the increase since March 2010 in the overall medical care component of the CPI–U published by the Department of Labor using the 1982–1984 base of 100. The medical care component of the CPI–U is a measure of the average change over time in the prices paid by urban consumers for medical care. Although the Departments continue to believe this is an appropriate measure for medical inflation in this context, the Departments recognize that the medical care component of CPI–U reflects not only changes in price for private insurance, but also for self-pay patients and Medicare, neither of which are reflected in the underlying costs for grandfathered group health plans and grandfathered group health insurance coverage. In contrast, the premium adjustment percentage reflects the cumulative, historic growth from 2013 through the preceding calendar year in premiums for only private health insurance, excluding Medigap and property and casualty insurance. Therefore, the Departments agree with comments that the premium adjustment percentage better reflects the increase in underlying costs for grandfathered group health plans and grandfathered group health insurance coverage. The Departments acknowledge that the premium adjustment percentage does not capture premium growth from 2010 to 2013, and that it reflects increases in premiums in the individual market, which have increased more rapidly than premiums for group health plans and group health insurance. However, the Departments believe the premium adjustment percentage is the best existing measure to reflect the increase in underlying costs for grandfathered group health plans and grandfathered group health insurance coverage. Additionally, the Departments believe using a measure with which plans and issuers are already familiar would increase administrative simplicity. Nevertheless, the Departments seek comment on alternative measures that more accurately represent the increase in underlying costs for grandfathered group health plans and grandfathered group health insurance coverage.

These proposed rules include an amended definition of the maximum percentage increase that provides an alternative standard that relies on the premium adjustment percentage, rather than medical inflation (which continues to be defined, for purposes of these rules, as the overall medical care component of the Consumer Price Index for All Urban Consumers, unadjusted), to account for changes in healthcare costs over time. This alternative standard would not supplant the current standard; rather, it would be available to the extent it yields a greater result than the current standard, and it would apply only with respect to increases in fixed-amount cost-sharing requirements that are made effective on or after the effective date of the final rule. With respect to increases for group health plans and group health insurance coverage made effective on or after March 23, 2010, and before the effective date of the final rule, the maximum percentage increase would still be defined as medical inflation expressed as a percentage, plus 15 percentage points.[15]

Thus, under these proposed rules, increases to fixed-amount cost-sharing requirements for grandfathered group health plans and grandfathered group health insurance coverage that are made

[13] For calendar year 2020, a ''high deductible health plan'' is defined under Code § 223(c)(2)(A) as a health plan with an annual deductible that is not less than $1,400 for self-only coverage or $2,800 for family coverage, and the annual out-of-pocket expenses (deductibles, co-payments, and other amounts, but not premiums) for which do not exceed $6,900 for self-only coverage or $13,800 for family coverage. Rev. Proc. 2019–25. For calendar year 2021, a ''high deductible health plan'' is defined under Code § 223(c)(2)(A) as a health plan with an annual deductible that is not less than $1,400 for self-only coverage or $2,800 for family coverage, and the annual out-of-pocket expenses (deductibles, co-payments, and other amounts, but not premiums) for which do not exceed $7,000 for self-only coverage or $14,000 for family coverage. Rev. Proc. 2020–32.

[14] Paragraph (g)(3) of the 2015 final rules would be renumbered as paragraph (g)(4), and subsequent paragraphs would be renumbered accordingly. Additionally, the proposed rules include conforming amendments to other paragraphs in the proposed rules to update all cross-references to those subparagraphs.

[15] The amendments included in these proposed rules would apply only with respect to grandfathered group health plans and grandfathered group health insurance coverage. Because HHS regulations at 45 CFR 147.140 apply to both grandfathered individual and group health coverage, the amended definition of the maximum percentage increase in the HHS proposed regulations would also add a separate provision for individual health insurance coverage to show that the applicable definition remains unchanged.

effective on or after the effective date of the final rule, would cause the plan or coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the greater of (1) medical inflation, expressed as a percentage, plus 15 percentage points; or (2) the portion of the premium adjustment percentage, as defined in 45 CFR 156.130(e), that reflects the relative change between 2013 and the calendar year prior to the effective date of the increase (that is, the premium adjustment percentage minus 1), expressed as a percentage, plus 15 percentage points. These proposed rules would also add a new example 5 under paragraph (g)(5) to demonstrate how this alternative measure for determining the maximum percentage increase might apply in practice. Similar to other examples in paragraph (g)(5), the new example 5 includes hypothetical numbers with respect to both the overall medical care component of the CPI–U and the premium adjustment percentage that do not relate to any specific time period and are used for illustrative purposes only. These proposed rules would also renumber examples 5–9 in paragraph (g)(5) to allow the inclusion of new example 5 and to revise examples 3–6 to clarify that these examples involve plan changes that become effective before the effective date of the final rule. These proposed revisions would ensure that the examples accurately reflect the other provisions of the rule.

Stakeholders reviewing these proposed rules should look to official publications from the Bureau of Labor Statistics and HHS to identify the relevant overall medical care component of the CPI–U amount or premium adjustment percentage with respect to a change being considered by a grandfathered health plan.

III. Effective Date

The amendments to the 2015 final rules that are included in these proposed rules would apply to grandfathered group health plans and grandfathered group health insurance coverage beginning 30 days after the publication of any final rules. The Departments solicit comment on this proposed effective date.

IV. Economic Impact Analysis and Paperwork Burden

A. Summary/Statement of Need

Section 1251 of PPACA provides that certain group health plans and health insurance coverage existing on March 23, 2010, are not subject to certain provisions of PPACA as long as they maintain grandfather status. On February 25, 2019, the Departments published an RFI to gather information on grandfathered group health plans and grandfathered group health insurance coverage. Comments received from stakeholders in response to the 2019 RFI suggest that issuers and plan sponsors, as well as participants and beneficiaries, continue to value the option to continue grandfathered group health plan and grandfathered group health insurance coverage. The Departments are of the view that these proposed rules would be appropriate to provide certain grandfathered health plans greater flexibility to make changes to certain types of cost-sharing requirements without causing a loss of grandfather status. These changes would allow certain grandfathered group health plans and grandfathered group health insurance coverage to continue to be exempt from certain provisions of PPACA and allow those plans' participants and beneficiaries to maintain their current coverage.

In drafting these proposed rules, the Departments attempted to balance a number of competing interests. For example, the Departments sought to balance providing greater flexibility to grandfathered group health plans and grandfathered group health insurance coverage that would enable these plans and coverage to continue offering quality, affordable coverage to participants and beneficiaries against ensuring that the proposed policies would not allow for such significant changes that the plan or coverage could not reasonably be described as being the same plan or coverage that was offered on March 23, 2010. Additionally, the Departments sought to allow grandfathered group health plans and grandfathered group health insurance coverage to better account for rising healthcare costs, including ensuring that grandfathered group HDHPs are able to maintain their grandfather status, while continuing to comply with minimum cost-sharing requirements for HDHPs, so that the individuals enrolled in the HDHPs are eligible to contribute to an HSA. In previous rulemaking, the Departments recognized that many group health plans and issuers make changes to the terms of plans or health insurance coverage on an annual basis: premiums fluctuate, provider networks and drug formularies change, employer and employee contributions and cost-sharing requirements change, and covered items and services may vary. Without some flexibility to make adjustments while retaining grandfather status, the ability of many individuals to maintain their current coverage would be frustrated, because much of the grandfathered group health plan coverage would quickly cease to be regarded as the same health plan or health insurance coverage in existence on March 23, 2010. At the same time, allowing plans to make unfettered changes while retaining grandfather status would be inconsistent with Congress's intent in enacting PPACA.[16]

These proposed rules, if finalized, would amend the 2015 final rules to provide greater flexibility for grandfathered group health plans and issuers of grandfathered group health insurance coverage in two ways. First, the proposed rules would specify that any grandfathered group health plan and grandfathered group health insurance coverage that is an HDHP may make changes to fixed-amount cost-sharing requirements that would otherwise cause a loss of grandfather status without causing a loss of grandfather status, but only to the extent those changes are necessary to comply with the requirements for HDHPs under section 223(c)(2) of the Code. Second, these proposed rules would include a revised definition of ''maximum percentage increase,'' which provides an alternative method of determining that amount that is based on the premium adjustment percentage.

B. Overall Impact

The Departments have examined the impacts of these proposed rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits,

[16] 75 FR 34538, 34546 (June 17, 2010).

reducing costs, harmonizing rules, and promoting flexibility. A regulatory impact analysis must be prepared for rules with economically significant effects ($100 million or more in any one year).

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a ''significant'' regulatory action is subject to Office of Management and Budget (OMB) review. As discussed below regarding their anticipated effects, these proposals are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of ''economically significant'' under Executive Order 12866. OMB has determined, however, that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these proposed rules and the Departments have provided the following assessment of their impact.

C. Impact Estimates of Grandfathered Group Health Plans and Grandfathered Group Health Insurance Coverage Provisions and Accounting Table

These proposed rules, if finalized, would amend the 2015 final rules to provide greater flexibility for grandfathered group health plan sponsors and issuers of grandfathered group health insurance coverage to make certain changes to cost-sharing requirements without causing a loss of grandfather status. The proposed rules would specify that issuers or sponsors of any grandfathered group health plan and grandfathered group health insurance coverage that is an HDHP may make changes to fixed-amount cost-sharing requirements that would otherwise cause a loss of grandfather status without causing a loss of grandfather status, but only to the extent those changes are necessary to comply with the requirements for HDHPs under section 223(c)(2) of the Code. The proposed rules would also revise the definition of ''maximum percentage increase'' to provide an alternative method of determining that amount that is based on the premium adjustment percentage. In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action.

The Departments are unable to quantify all benefits, costs, and transfers of these proposed rules. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs and transfers resulting from the provisions of these proposed rules for plans, issuers, participants, and beneficiaries.

TABLE 1—ACCOUNTING TABLE

Benefits

Non-Quantified:

- Allows sponsors of grandfathered group health plans and grandfathered group health insurance coverage more flexibility to make changes to certain fixed-amount cost-sharing requirements without losing grandfather status.
- Allows participants and beneficiaries in grandfathered group health plans and grandfathered group health insurance coverage to maintain coverage they are familiar with and potentially provides continuity of care by not requiring them to change their health plan to one that may not include their current provider(s).
- Ensures plan sponsors are able to comply with minimum cost-sharing requirements for HDHPs and allows participants and beneficiaries to maintain their coverage and eligibility to contribute to an HSA.
- Decreases the likelihood that plan sponsors would cease offering health benefits due to a lack of flexibility to make changes to certain fixed cost-sharing amounts without losing grandfather status.

Costs:	Primary estimate (million)	Year dollar	Discount rate (percent)	Period covered
	$7.95	2020	7	2021–2025
Annualized Monetized ($/year)	7.40 million	2020	3	2021–2025

Quantitative:

- Regulatory review costs of $34.9 million, incurred in 2020 only, by grandfathered group health plan coverage sponsors and issuers.

Non-Quantified:

- Potential increase in adverse health outcomes if a participant or beneficiary would forego treatment because the necessary services became unaffordable due to an increase in cost sharing.
- Potential increase in adverse health outcomes if there is an increase in the uninsured rate if participants and beneficiaries choose to cancel their coverage because of the increases in cost-sharing requirements associated with grandfathered group health plans and grandfathered group health insurance coverage.
- If an employer would have otherwise switched to a non-grandfathered plan, potential increase in adverse health outcomes if a participant or beneficiary foregoes treatment for medical conditions that are not covered by their grandfathered group health plan and grandfathered group health insurance coverage but that would have been covered by non-grandfathered health plan coverage subject to PPACA.

Transfers
Non-Quantified: • In grandfathered group health plans and grandfathered group health insurance coverage that utilize the expanded flexibilities to increase fixed-amount cost-sharing requirements, potential transfers occur from participants and beneficiaries with resulting higher out-of-pocket costs to participants and beneficiaries with no or low out-of-pocket costs and nonparticipants through potentially lower premiums and correspondingly smaller wage adjustments to pay for the premiums. • If an employer would have otherwise switched to a non-grandfathered plan with expanded benefits, potential transfers occur from participants and beneficiaries who would have benefited from these expanded benefits to others in the plan who would not have benefited from these expanded benefits through lower premiums and correspondingly smaller wage adjustments.

Table 1 provides the anticipated benefits, costs, and transfers (quantitative and non-quantified) to sponsors and issuers of grandfathered health plan coverage, participants and beneficiaries enrolled in grandfathered plans, as well as nonparticipants. The following section describes the benefits, costs, and transfers to grandfathered group health plan sponsors, issuers of grandfathered group health insurance coverage, and those individuals enrolled in such plans.

These proposed rules propose a new paragraph (g)(3) which would specify that grandfathered group health plans and grandfathered group health insurance coverage that are HDHPs may increase fixed-amount cost-sharing requirements that otherwise would cause a loss of grandfather status, without causing the plan or coverage to relinquish its grandfather status, but only to the extent the increases are necessary to comply with the requirements for HDHPs under section 223(c)(2) of the Code. Additionally, the proposed rules propose a revised definition of ''maximum percentage increase'' in redesignated paragraph (g)(4) to provide an alternative method of determining that amount that is based on the premium adjustment percentage.

Economic Impacts of Retaining or Relinquishing Grandfather Status and Affected Entities and Individuals

The Departments estimate that there are 2.4 million ERISA-covered plans offered by private employers that cover an estimated 134.7 million participants and beneficiaries in those private employer-sponsored plans.[17] Similarly, the Departments estimate that there are 83,500 state and local governments that offer health coverage to their employees, with an estimated 42.8 million participants and beneficiaries in those employer-sponsored plans.[18]

The 2019 Employer Health Benefits Survey reports that 22 percent of firms offering health benefits have at least one health plan or benefit package option that is a grandfathered plan, and 13 percent of covered workers are enrolled in grandfathered plans.[19] Using the above information, the Departments estimate that, of those firms offering health benefits, 527,000 sponsor ERISA-covered plans (2.4 million * 0.22) that are grandfathered (or include a grandfathered benefit package option) and cover 17.5 million participants and beneficiaries (134.7 million * 0.13). The Departments further estimate there are 18,400 state and local governments (83,500 * 0.22) offering at least one grandfathered health plan and 5.6 million participants and beneficiaries (42.8 million * 0.13) covered by a grandfathered state or local government plan.

Although the 2019 Employer Health Benefits Survey reports that 26 percent of firms offering health benefits offered an HDHP and 23 percent of covered workers were enrolled in HDHPs, the Departments believe the 2010 Employer Health Benefits Survey provides a better estimate of the prevalence of HDHPs in the grandfathered group market as it provides an estimate for the number of potential HDHPs that would have been able to obtain and maintain grandfather status. The 2010 Employer Health Benefits Survey reports that 12 percent of firms offering health benefits offered an HDHP, and 6 percent of covered workers were enrolled in HDHPs.[20]

Benefits

The Departments believe that the economic effects of these proposed rules would ultimately depend on any decisions made by grandfathered plan sponsors (including sponsors of grandfathered HDHPs) and the preferences of plan participants and beneficiaries. To determine the value of retaining a health plan's grandfather status, each group plan sponsor must determine whether the plan, under the rules applicable to grandfathered health plan coverage, would continue to be more or less favorable than the plan, under the rules applicable to non-grandfathered group health plans. This determination would depend on such factors as the respective prices of grandfathered and non-grandfathered health plans, the willingness of grandfathered group health plans' covered populations to pay for benefits and protections available under non-grandfathered health plans, and their willingness to accept any increases in out-of-pocket costs due to changes to certain types of cost-sharing requirements. The Departments are of the view that providing the proposed flexibilities to make changes to certain types of cost-sharing requirements in grandfathered group health plans and grandfathered group health insurance coverage without causing a loss of grandfather status would enable plan sponsors and issuers to continue to offer quality, affordable coverage to their participants and beneficiaries while taking into account rising health care costs.

The Departments anticipate that the premium adjustment percentage index will continue to experience faster growth than medical CPI–U, and therefore believe that providing the proposed alternative method of determining the ''maximum percentage

[17] The Department of Labor estimates based on the 2018 Medical Expenditure Panel Survey Insurance Component (MEPS–IC), available at *https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2018/ic18_ia_g.pdf;* Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey, Table 3C, available at *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[18] 2017 Census of Governments, Government Organization Report, available at *https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html;* 2017 MEPS–IC State and Local Government data, available for query at *https://meps.ahrq.gov/mepsweb/data_stats/MEPSnetIC/startup;* Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey, Table 3C, available at *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[19] The Departments note that comments received in response to the 2019 RFI and summarized earlier in this preamble described data obtained from Kaiser Family Foundation 2018 Employer Health Benefits Survey. See *supra* note 9. For the purposes of this regulatory impact analysis, the Departments used more recent data from the same survey. See Kaiser Family Foundation, ''2019 Employer Health Benefits Survey,'' available at *https://www.kff.org/health-costs/report/2019-employer-health-benefits-survey/.*

[20] Kaiser Family Foundation, ''2010 Employer Health Benefits Survey.'' Available at: *https://www.kff.org/wp-content/uploads/2013/04/8085.pdf.*

increase'' would, over time, give grandfathered group health plans and grandfathered group health insurance coverage the flexibility to make changes to the plans' fixed-amount cost-sharing requirements (such as copayments, deductibles, and out-of-pocket limits) that would have previously resulted in the loss of grandfather status. Thus, the Departments believe that these proposed rules would allow sponsors of those grandfathered health plans to continue to provide the coverage with which their participants and beneficiaries are familiar and comfortable, without the unnecessary burden of finding other coverage.

As noted previously in the preamble, some commenters suggested that their grandfathered plans offer more robust provider networks than other coverage options available to them or that they want to ensure that participants and beneficiaries are able to keep receiving care from current in-network providers. The Departments agree that providing the proposed flexibilities could help participants and beneficiaries maintain their current provider and service networks. If providers continue participating in the grandfathered plans' networks, this continuity offers participants and beneficiaries the ability to continue current and future care through those providers with whom they have built relationships.

As discussed previously in the preamble, one commenter on the 2019 RFI articulated a concern that the 2015 final rules may eventually preclude some sponsors and issuers of grandfathered group health plans and grandfathered group health insurance coverage from being able to make changes to fixed-amount cost-sharing requirements necessary to maintain a plan's HDHP status. For participants and beneficiaries, this would mean they could experience either substantial changes to their coverage (and likely premium increases) or a loss of eligibility to contribute to an HSA. The Departments expect that, under the 2015 final rules, there may be limited circumstances in which grandfathered group health plans and grandfathered group health insurance coverage that is an HDHP (grandfathered HDHP) is unable to simultaneously maintain its grandfather status and satisfy the requirements for HDHPs under section 223(c)(2) of the Code. To reduce the likelihood of this potential scenario, these proposed rules would allow a grandfathered HDHP to make changes to fixed-amount cost-sharing requirements that otherwise could cause a loss of grandfather status without causing a loss of grandfather status, but only to the extent the increases are necessary to comply with the requirements for HDHPs under section 223(c)(2) of the Code.

The Departments are of the view that providing this flexibility to grandfathered HDHPs will allow them to preserve their grandfather status even if they increase their cost-sharing requirements to meet a future adjusted minimum annual deductible requirement under section 223(c)(2)(A) of the Code beyond the increase that would be permitted under paragraph (g)(1) of the 2015 final rules. Under section 223(g) of the Code, the required minimum deductible for an HDHP is adjusted for cost-of-living based on changes in the overall economy. Historically, the allowed increases under the 2015 final rules, which are based on changes in medical care costs (medical CPI–U), have exceeded increases based on changes in the overall economy (CPI–U), which are used to adjust the HDHP minimum deductible. Using ten years of projections from the President's FY 2021 Budget, medical-CPI–U is expected to grow faster than CPI–U. Further, because the allowed increases under the 2015 final rules are based on the cumulative effect over a period of years, it is unlikely that using medical CPI–U to index deductibles would result in lower deductibles than using CPI–U as required under section 223(g) of the Code. Therefore, the Departments note that, to the extent these trends continue, it is unlikely that an increase required under section 223 of the Code for a plan to remain an HDHP would exceed the allowed increases under the 2015 final rules. Furthermore, to the extent that the revised definition of ''maximum percentage increase'' in these proposed rules would allow the deductible to grow as fast, or faster, than under the 2015 final rules, grandfathered HDHPs may not need to avail themselves of the additional flexibility provided in these proposed rules. Nevertheless, the Departments are of the view that affording this flexibility would make the rules more transparent to sponsors of grandfathered HDHPs. Thus, the proposed regulations would allow participants and beneficiaries enrolled in those plans to maintain their current coverage, continue contributing to any existing HSA, and potentially realize any reduction in premiums that may result from changes in cost-sharing requirements.

Costs and Transfers

The Departments recognize there may be costs associated with these proposed rules that are difficult to quantify given the lack of information and data. For example, the Departments do not have data related to the current annual out-of-pocket costs for participants and beneficiaries in grandfathered group HDHPs or other grandfathered group health plans and grandfathered group health insurance coverage. The Departments recognize that as medical care costs increase, some participants and beneficiaries in grandfathered health plans could face higher out-of-pocket costs for services that may be excluded by such plans, but that would be required or covered by non-grandfathered group health plans and group health insurance coverage subject to PPACA. It is possible these increased costs could be (partially) offset by lower premiums from participation in the grandfathered plans. Further, participants and beneficiaries who would otherwise be covered by a non-grandfathered plan could potentially face increases in adverse health outcomes if they chose to forego treatment because certain services are not covered by their grandfathered group plan or grandfathered group health insurance coverage. The Departments cannot accurately predict the number of grandfathered health plans and group health insurance coverage that would retain their grandfather status should they choose to avail themselves of the flexibilities provided in these proposed rules. The 2019 Employer Health Benefits Survey reports no significant change from 2018 in the number of firms offering at least one grandfathered health plan or the number of covered individuals.[21] A large change would have indicated that the current rules were too restrictive and that a relaxation of those rules would have a big effect. The actual small change suggests the opposite. Therefore, the Departments do not expect a significant impact on the number of grandfathered plans or group health insurance coverage as a result of these proposed rules.

For those plans that would continue to maintain their grandfather status as a result of the flexibilities in these proposed rules, the participants and beneficiaries would continue to have coverage and may experience lower premiums when compared to non-grandfathered group health plans. Although some participants and beneficiaries would pay higher cost-sharing amounts, these increased costs may be partially offset by reduced

[21] Kaiser Family Foundation, ''2019 Employer Health Benefits Survey,'' available at *https://www.kff.org/health-costs/report/2019-employer-health-benefits-survey/*.

employee premiums, and indirectly through wage adjustments that reflect reduced employer contributions due to the lower premiums. In contrast, individuals who have low or no medical expenses, along with nonparticipants, would be unlikely to experience increased cost-sharing amounts and may benefit from lower employee premiums, and indirectly through wage adjustments.

The Departments recognize there would be transfers associated with these proposed rules that are difficult to quantify given the lack of information and data. The Departments realize that if plan sponsors avail themselves of the flexibilities in these proposed rules, some participants and beneficiaries of grandfathered group health plans and grandfathered group health insurance coverage could potentially see increases in out-of-pocket costs depending on the changes made to their plans. Additionally, participants and beneficiaries in a grandfathered HDHP could face increases in the plan's deductible if plans increase their fixed-amount cost-sharing requirements to meet a future adjusted minimum annual deductible requirement beyond the increase that would be permitted under paragraph (g)(1). Changes in costs associated with increased deductibles or other cost sharing would be a transfer from participants and beneficiaries with high out-of-pocket costs to participants and beneficiaries with low or no out-of-pocket costs and to nonparticipants, as the related premium reductions could affect wages.

Due to the overall lack of information and data related to what plan sponsors would choose to do, the Departments are unable to accurately determine the overall economic impact, but the Departments anticipate that the overall impact would be minimal. However, there is a large degree of uncertainty regarding the effect of the proposed rules on any potential changes to cost sharing at the plan level so actual experience could differ.

Revenue Impact of Proposed Rules

This section of the preamble discusses the revenue impact of the proposed rules, considers a variety of approaches that employers offering grandfathered health plan coverage might take in the future if the 2015 final rules are not amended, and compares the revenue impact of each approach under the 2015 final rules with the revenue impact under the proposed rules.

a. Employees Who Would Have Remained in Grandfathered Plans and Coverage Without the Proposed Rules

If the 2015 final rules are not amended, some employers might choose to continue to maintain their grandfathered health plan coverage. This subsection discusses the revenue impact that the proposed rules may have on this group of employers and employees.

Under the proposed rules, grandfathered group health plans and grandfathered group health insurance coverage would be allowed to increase fixed-amount cost-sharing requirements (such as copayments, deductibles, and out-of-pocket limits) at a somewhat higher rate than under the 2015 final rules, which may result in a premium reduction (or similar cost reduction for a self-insured plan). Specifically, for increases in fixed-amount cost sharing on or after the effective date of these rules, if finalized, grandfathered group health plans and grandfathered group health insurance coverage could use an alternative standard for determining the maximum percentage increase that relies on the premium adjustment percentage, rather than medical inflation, to the extent that it yields a greater result than the current standard under the 2015 final rules.

The premium adjustment percentage is estimated to be about three percentage points higher than medical inflation in 2026, using FY2021 President's Budget projections of medical CPI and National Health Expenditures premium projections. Therefore, as of that year, fixed-amount copayments, deductibles, and out-of-pocket limits could be three percentage points higher under the proposed rules than under the 2015 final rules. However, a plan that increases fixed-amount cost sharing to the maximum amount allowed under the proposed rules is likely to realize only a small reduction in premiums. This is because plans incur most of their costs for a relatively small fraction of participants—that is, from high-cost individuals. Because high-cost individuals generally exceed the out-of-pocket limit for the year, they are only modestly affected by higher out-of-pocket limits. Low-cost individuals are more likely to be affected by an increase in fixed-amount cost sharing, but they incur a small portion of the overall costs. Therefore, the impact of the proposed rules for a particular plan will depend on the parameters of covered benefits under the plan, as well as the distribution of expenditures for the plan participants. In addition, increased cost sharing could result in participants and beneficiaries making fewer visits to providers (that is, lower utilization), which could result in lower medical costs for some individuals, but higher costs for others who delay important visits. If individuals generally would forgo relatively unimportant visits, but continue to go to providers when crucial, premiums could decline even more, but this outcome is uncertain.

Because of the Federal tax exclusion for employer-sponsored coverage, a premium reduction would increase tax revenues due to reduced employer contributions and employee pre-tax contributions made through a cafeteria plan. However, some employees might partially offset their increases in out-of-pocket payments through increased pre-tax contributions to health flexible spending arrangements (FSAs) or HSAs. Those increases in pre-tax contributions to health FSAs and HSAs would reduce tax revenues. Therefore, the potential increase in tax revenues from premium reductions is affected by whether employees increase their contributions to health FSAs and HSAs. To the extent that employers would have continued to offer a grandfathered plan without changes to the 2015 final rules, under the proposed rules, tax revenues would be expected to increase slightly on net as a result of premium reductions. Further, there would be additional revenue gains to the extent that higher out-of-pocket payments discourage employees from continuing participation in the employer's plan.

b. Employees Who Would No Longer Have Been Covered by Grandfathered Plans or Coverage Without the Proposed Rules

If the 2015 final rules are not amended, some employers might choose to change their insured grandfathered plans to self-insured, non-grandfathered plans, rather than continue to comply with the 2015 final rules, which would result in little, if any, revenue change. Thus, with respect to these employers, the adoption of the proposed rules would have little, if any, revenue effect.

Alternatively, assuming the 2015 final rules are not amended, an employer might switch to a fully insured non-grandfathered non-HDHP plan. With respect to small employers, employees who would transfer to the non-grandfathered plan could improve the risk pool or make it worse. An employer with a healthy population might be more likely to self-insure, whereas a small employer with a less healthy population might be more likely to join an insurance pool.

Although the type of benefits covered in the new, non-grandfathered plans

(whether self-insured or fully insured) would likely be broader in some ways, such as for preventive care, the share of costs covered by the plan would likely decrease due to higher cost sharing. Presumably, if the 2015 final rules are not amended, an employer would not make the switch from a grandfathered plan to a non-grandfathered plan unless the overall cost of providing benefits would decrease, which would cause some revenue gain. (Again, though, the revenue gain could be partially offset by increases in the employees' pre-tax contributions to health FSAs or HSAs.) On the other hand, if the proposed rules enabled an employer that otherwise might switch to a non-grandfathered plan to retain its grandfathered plan, this revenue gain would not occur, resulting in a revenue loss compared to the status quo under the 2015 final rules. As a further variation, if the employer retained its grandfathered plan under the proposed rules, rather than switching to an HDHP, the revenue loss would be smaller than if the employer had switched to a non-HDHP. Indeed, this could even result in a revenue gain depending on the magnitude of tax-preferred contributions that the employees would have made to HSAs.

Without the change to the 2015 final rules, some employers might replace their grandfathered plan with an individual coverage health reimbursement arrangement (individual coverage HRA). If the employer contributed a similar dollar amount to the individual coverage HRA as it currently does to the grandfathered plan, the employees' tax exclusion would be at least roughly the same as for the grandfathered plan. Moreover, the employees offered the individual coverage HRA would be as likely to be ''firewalled'' from obtaining a premium tax credit as if they had continued to participate in the grandfathered plan. Thus, under this scenario, there would be very little revenue effect from the proposed rules.

c. Termination of Employer-Sponsored Coverage

If the 2015 final rules are not amended, some employers might drop health coverage altogether and opt instead to make an employer shared responsibility payment, if required under section 4980H of the Code, which may result in an increase in federal revenue. In this case, all affected employees would qualify for a special enrollment period to enroll in other group coverage, if available, or individual health insurance coverage on or off the Exchange. Those employees with household incomes between 100–400 percent of the federal poverty level may qualify for financial assistance to help pay for their Exchange coverage and related healthcare expenses, which would increase federal outlays, as discussed further below. Others may have household incomes too high to be eligible for a premium tax credit or might receive a smaller tax subsidy through the income-related premium tax credit than through an employer-sponsored health insurance tax exclusion. Accordingly, if these employers continued their grandfathered plan under the proposed rules, there may be an associated revenue loss. Other employees could purchase individual health insurance coverage, but receive a premium tax credit that is greater than the value of the tax exclusion for their current employer plans. For this population, the proposed rules may result in a revenue gain. However, this is likely a small population for an employer that is currently offering a grandfathered plan.

Despite the availability of a special enrollment period, some affected employees might forgo enrolling in alternative health coverage and become uninsured or might opt instead to purchase short-term, limited-duration insurance. In this case, these employees would no longer receive a tax exclusion for the grandfathered plan, which along with an employer shared responsibility payment, if any, may result in an increase in federal revenue. However, if these employees were to remain covered under a grandfathered plan as a result of this proposed rule, there may be a loss in federal revenue for this group.

Overall, there are a number of potential revenue effects of the proposed rules, some of which could offset each other. Additionally, there is a large degree of uncertainty, including uncertainty with regard to how many plans would continue as grandfathered plans if the 2015 final rules are not amended, what alternatives would be chosen by the employers who do not keep grandfathered plans, and how many plans would make plan design changes as a result of the proposed rules. As a result, it is unclear whether these effects in the aggregate would result in a revenue gain or revenue loss. Because the employer market is so large, even a small percentage change to aggregate premiums can result in large revenue changes. Nevertheless, the Departments are of the view that overall net effects are likely to be relatively small. The Departments seek comments on the impact estimates in this analysis.

Regulatory Review Costs

Affected entities will need to understand the requirements of these proposed rules, if finalized, before they can avail themselves of any of the proposed flexibilities. Sponsors and issuers of grandfathered group health plan coverage would be responsible for ensuring compliance with these proposed rules should they seek to make changes to their plans' cost-sharing requirements. The Departments estimate the burden for the regulatory review to be incurred by the 546,234 grandfathered plan sponsors and issuers of grandfathered group health insurance coverage.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret these proposed rules, if finalized, the Departments should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review and interpret these proposed rules, the Departments assume that the total number of grandfathered group health plan coverage sponsors and issuers that would be able to avail themselves and comply with these proposed rules would be a fair estimate of the number of entities affected.

The Departments acknowledge that this assumption may understate or overstate the costs of reviewing these proposed rules. It is possible that not all affected entities will review these rules, if finalized, in detail, and that others may seek the assistance of outside counsel to read and interpret the rules. For example, firms providing or sponsoring a grandfathered plan may not read the rules, if finalized, but might rely upon the issuer or a third-party administrator (TPA), if self-funded, to read and interpret the rules. For these reasons, the Departments are of the view that the number of grandfathered group health plan coverage sponsors and issuers would be a fair estimate of the number of reviewers of these proposed rules. The Departments welcome any comments on the approach in estimating the number of affected entities that will review and interpret these proposed rules, if finalized.

Using the wage information from the Bureau of Labor and Statistics (BLS) for a Compensation and Benefits Manager (Code 11–3141), the Departments estimate that the cost of reviewing this rule is $127.74 per hour, including overhead and fringe benefits.[22]

[22] Wage information is available at *https://www.bls.gov/oes/current/oes_nat.htm.* Hourly wage

Continued

Assuming an average reading speed, the Departments estimate that it would take approximately 0.5 hour for the staff to review and interpret these proposed rules, if finalized; therefore, the Departments estimate that the cost of reviewing and interpreting these proposed rules, if finalized, for each grandfathered group health plan coverage sponsor and issuer is approximately $63.87. Thus, the Departments estimate that the overall cost for the estimated 546,234 grandfathered group health plan coverage sponsors and issuers would be $34,887,965.58 ($63.87 *546,234 total number of estimated grandfathered plan sponsors and issuers).[23]

D. Regulatory Alternatives Considered

In developing the policies contained in these proposed rules, the Departments considered alternatives to the presented proposals. In the following paragraphs, the Departments discuss the key regulatory alternatives considered.

The Departments considered whether to modify each of the six types of changes, measured from March 23, 2010, that cause a group health plan or health insurance coverage to cease to be grandfathered. To provide more flexibility regarding changes to fixed cost-sharing requirements, the Departments considered revising the definition of maximum percentage increase to increase the allowed percentage points that are added to medical inflation. However, the Departments are of the view that the proposed policy allows for the desired flexibility, while better reflecting underlying costs for grandfathered group health plans and group health insurance coverage. The Departments acknowledge that the premium adjustment percentage, which the Departments propose to incorporate into the definition of ''maximum percentage increase,'' reflects the changes in premiums in both the individual and group market, and that individual market premiums have increased faster than premiums in the group market. Due to the comparative sizes of the individual and group markets, however, the historically faster growth in the individual market has had a minimal impact on the premium adjustment percentage index. Therefore, the Departments believe that the premium adjustment percentage is an appropriate measure to incorporate into the definition of ''maximum percentage increase.''

Another option the Departments considered was allowing a decrease in contribution rates by an employer or employee organization without triggering a loss of grandfather status. Under the 2015 final rules, an employer or employee organization cannot decrease contribution rates based on cost of coverage toward the cost of any tier of coverage for any class of similarly situated individuals by more than five percentage points below the contribution rate for the coverage period that included March 23, 2010 without losing grandfather status. The Departments considered permitting group health plans and health insurance coverage with grandfather status to decrease the contribution rates by more than five percentage points. This would increase employer flexibility, but the Departments were concerned that a decrease in the contribution rate could change the plan or coverage to such an extent that the plan or coverage could not reasonably be described as being the same plan or coverage that was offered on March 23, 2010. As a result, this option was not included in the proposed rules.

Another option the Departments considered was allowing a change to annual dollar limits for a group health plan or health insurance coverage without triggering a loss of grandfather status. Under the 2015 final rules, a group health plan or group health insurance coverage that did not have an annual dollar limit on March 23, 2010, may not establish an annual dollar limit for any individual, whether provided in-network or out-of-network, without relinquishing grandfather status. If the plan or coverage had an annual dollar limit on March 23, 2010, it may not decrease the limit. Although for plan years beginning on or after January 1, 2014, group health plans and health insurance issuers generally may no longer impose annual or lifetime dollar limits on essential health benefits, permitting changes to annual dollar limits on benefits that are not essential health benefits may still represent a significant change to participants and beneficiaries who need the benefits on which a limit is applied. Therefore, this option was not included in the proposed rules.

The Departments considered options to offset cost-sharing requirement changes by allowing sponsors of group health plans and issuers of group health insurance coverage to increase different types of cost-sharing requirements as long as any increase is offset by lowering another cost-sharing requirement to preserve the plan's actuarial value. As discussed in previous rulemaking, however, an actuarial equivalency standard would allow a plan or coverage to make fundamental changes to the benefit design, potentially conflicting with the goal of allowing participants and beneficiaries to retain health plans they like, and still retain grandfather status.[24] There would also be significant complexity involved in defining and determining actuarial value for these purposes, as well as significant burdens associated with administering and ensuring compliance with such rules. Therefore, the Departments did not include this option in the proposed rules.

The Departments considered changing the date of measurement for calculating whether changes to group health plans or health insurance coverage will cause a loss of grandfather status. For example, instead of looking at the cumulative change from March 23, 2010, the rules could measure the annual increases, starting from the effective date of the proposed rules, if finalized. However, the Departments concluded that this option could limit flexibility for some employers. For example, some employers might want to keep the terms of the plan the same for a few years and then make a more significant change later.

The Departments also considered making changes to the 2015 final rules to encourage more cost-effective care. One option the Departments considered to encourage cost-effective care was allowing greater cost sharing for brand name drugs if a generic becomes available. However, the Departments decided not to make this change because allowing greater cost-sharing for brand name drugs when a generic becomes available does not result in loss of grandfather status under the 2015 final rules.[25] Another option the Departments considered was allowing unlimited changes to cost sharing for out-of-network benefits. However, the Departments are concerned that unlimited discretion to change cost-

rate is determining by multiplying the mean hourly wage by 100 percent to account for overhead and fringe benefits. The mean hourly wage for a Compensation and Benefit Manager (Code 11–3141) is $63.38, when multiplied by 100 percent results in a total adjusted hourly wage of $127.74.

[23] Total number of grandfathered plan sponsors and issuers of grandfathered group health insurance coverage, discussed earlier in the preamble, was derived from the total number of ERISA covered plan sponsors multiplied by the percentage of entities offering grandfathered health plans (2.4 million * 0.22 = 527,000), the number of state and local governments multiplied by the percentage of entities offering grandfathered health plans (83,500 * 0.22 = 18,400), and the 834 issuers offering at least one grandfathered health plan (527,000 + 18,400 + 843 = 546,234).

[24] 75 FR 34538, 34547 (June 17, 2010).

[25] 80 FR 72192, 72197, 72198 (Nov. 18, 2015).

sharing requirements for out-of-network benefits could result in changes to plans of such a magnitude that they no longer resemble the plan as it existed as of March 23, 2010. Additionally, the Departments decided that the proposal to change the applicable index for medical inflation provides sufficient flexibility for fixed cost-sharing requirements. This option would give flexibility to grandfathered plans with respect to all fixed-amount cost-sharing requirements, including for out-of-network benefits.

E. Collection of Information Requirements

These proposed rules do not impose new information collection requirements; that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Though the proposed rules do not contain any new information collection requirements, the Departments are continuing the current requirements that grandfathered plans maintain records documenting the terms of the plan in effect on March 23, 2010, include a statement in any summary of benefits that the plan or coverage believes it is grandfathered health plan coverage and provide contact information for participants to direct questions and complaints. Additionally, the Departments are continuing the requirement that a grandfathered group health plan that is changing health insurance issuers is required to provide the succeeding health insurance issuer documentation of plan terms under the prior health insurance coverage sufficient to make a determination whether the standards of paragraph 26 CFR 54.9815–1251(g)(1), 29 CFR 2590.715–1251(g)(1) and 45 CFR 147.140(g)(1) are exceeded and that insured group health plans (or multiemployer plans) that are grandfathered plans are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year. The Departments do not anticipate that the proposed provisions would make a substantive or material modification to the collections currently approved under the collection of information OMB control number 0938–1093 (CMS–10325), OMB control number 1210–0140 (DOL), and OMB control number 1545–2178 (Department of the Treasury).

F. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of proposed rules on small entities, unless the head of the agency can certify that the rules would not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than three to five percent as its measure of significant economic impact on a substantial number of small entities.

These proposed rules would amend the 2015 final rules to allow greater flexibility for grandfathered group health plans and issuers of grandfathered group health insurance coverage. Specifically, the proposed rules would specify that grandfathered group health plans that are HDHPs may make changes to fixed-amount cost-sharing requirements that would otherwise cause a loss of grandfather status without causing a loss of grandfather status, but only to the extent those changes are necessary to comply with the requirements for being HDHPs under section 223(c)(2) of the Code. The proposed rules would also include a revised definition of ''maximum percentage increase'' that would provide an alternative method of determining the ''maximum percentage increase'' that is based on the premium adjustment percentage.

G. Impact of Regulations on Small Business—Department of Health and Human Services and the Department of Labor

The Departments are of the view that health insurance issuers would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $41.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $35 million or less.[26] Few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report submissions for the 2018 MLR reporting year, approximately 84 out of 498 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less.[27] This estimate may overstate the actual number of small health insurance companies that may be affected, since over 72 percent of these small companies belong to larger holding groups. Most, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $41.5 million, and it is likely not all of these companies offer grandfathered plans. The Departments do not expect any of these 84 potentially small entities to experience a change in revenues of more than three to five percent as a result of these proposed rules. Therefore, the Departments do not expect the provisions of these proposed rules to affect a substantial number of small entities. Due to the lack of knowledge regarding what small entities may decide to do with regard to the provisions proposed in these proposed rules, the Departments are not able to accurately ascertain the economic effects on small entities. However, the Departments believe that the flexibilities provided for in these proposed rules would result in overall benefits for small entities by allowing them to make changes to certain cost-sharing requirements within limits and maintain their current grandfathered group health plans. The Departments seek comment on ways that the proposed rules may impose additional costs and burdens on small entities.

For purposes of analysis under the RFA, the Employee Benefits Security Administration (EBSA) continues to consider a small entity to be an employee benefit plan with fewer than 100 participants.[28] The basis of this definition is found in section 104(a)(2)

[26] ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes.'' U.S. Small Business Administration, available at *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf.*

[27] ''Medical Loss Ratio Data and System Resources.'' CCIIO, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[28] The Department of Labor consulted with the Small Business Administration in making this determination as required by 5 U.S.C. 603(c) and 13 CFR 121.903(c).

of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans that cover fewer than 100 participants. Under section 104(a)(3), the Secretary of Labor may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of section 104(a)(3), the Department of Labor has previously issued at 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46, and 2520.104b–10 certain simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans covering fewer than 100 participants and satisfying certain other requirements. Further, while some large employers may have small plans, in general small employers maintain most small plans. Thus, EBSA believes that assessing the impact of these proposed rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*). Therefore, EBSA requests comments on the appropriateness of the size standard used in evaluating the impact of these proposed rules on small entities.

H. Impact of Regulations on Small Business—Department of the Treasury

Pursuant to section 7805(f) of the Code, these proposed rules have been submitted to the Chief Counsel for Advocacy of the SBA for comment on their impact on small business.

I. Effects on Small Rural Hospitals

Section 1102(b) of the Social Security Act (SSA) (42 U.S.C. 1302) requires agencies to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the SSA, the HHS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. These proposed rules would not affect small rural hospitals. Therefore, the Departments have determined that these proposed rules would not have a significant impact on the operations of a substantial number of small rural hospitals.

J. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain actions before issuing a proposed rule that includes any federal mandate that may result in expenditures in any one year by state, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million.

While the Departments recognize that some state, local, and tribal governments may sponsor grandfathered health plan coverage, the Departments do not expect any state, local, or tribal government to incur any additional costs associated with these proposed rules, if finalized. The Departments estimate that any costs associated with the proposed rules if finalized would not exceed the $156 million threshold. Thus, the Departments conclude that these proposed rules would not impose an unfunded mandate on state, local, or tribal governments or the private sector.

K. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. Federal agencies promulgating regulations that have federalism implications must consult with state and local officials and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

In the Departments' view, these proposed rules do not have any federalism implications. They simply provide grandfathered plan sponsors and issuers more flexibility to increase fixed-amount cost-sharing requirements and to make changes to fixed-amount cost-sharing requirements in grandfathered group health plans and grandfathered group health insurance coverage that are HDHPs to the extent those changes are necessary to comply with the requirements for HDHPs under section 223(c)(2) of the Code, without causing the plan or coverage to relinquish its grandfather status. The Departments recognize that some state, local, and tribal governments may sponsor grandfathered health plan coverage. The proposed rules would provide these entities with additional flexibility.

In general, through section 514, ERISA supersedes state laws to the extent that they relate to any covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. While ERISA prohibits states from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements in title XXVII of the PHS Act (including those enacted by PPACA) are not to be ''construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a ''requirement of a federal standard.'' The conference report accompanying HIPAA indicates that this is intended to be the ''narrowest'' preemption of states laws (see House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018). States may continue to apply state law requirements to health insurance issuers except to the extent that such requirements prevent the application of PHS Act requirements that are the subject of this rulemaking. Accordingly, states have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, the Departments have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis. While developing these proposed rules, the Departments attempted to balance the states' interests in regulating health insurance issuers with Congress' intent to provide uniform minimum protections to consumers in every state. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these proposed rules, the Departments certify that the Department of Treasury,

Employee Benefits Security Administration, and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached proposed rules in a meaningful and timely manner.

L. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017, and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' The designation of these proposed rules under Executive Order 13771—as a regulatory action, a deregulatory action, or neither—will be informed by comments received.

V. Statutory Authority

The Department of the Treasury regulations are proposed to be adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are proposed to be adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; section 101(g), Public Law 104–191, 110 Stat. 1936; section 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); section 512(d), Public Law 110–343, 122 Stat. 3881; section 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 6–2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services regulations are proposed to be adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Sunita Lough,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Signed at Washington DC, this 6th day of July, 2020.

Jeanne Klinefelter Wilson,

Acting Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

Dated: July 1, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 6, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Amendments to the Regulations

Accordingly, the Internal Revenue Service, Department of the Treasury, proposes to amend 26 CFR part 54 as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805.

* * * * *

■ **Par. 2.** Section 54.9815–1251, as amended:

■ a. By revising the first sentence of paragraph (g)(1) introductory text;

■ b. By revising paragraphs (g)(1)(iii), (g)(1)(iv)(A) and (B), and (g)(1)(v);

■ c. By redesignating paragraphs (g)(3) and (4) as paragraphs (g)(4) and (5);

■ d. By adding a new paragraph (g)(3);

■ e. By revising newly redesignated paragraphs (g)(4)(i) and (ii);

■ f. In newly redesignated paragraph (g)(5), by revising Examples 3 and 4;

■ g. In newly redesignated paragraph (g)(5), by redesignating Examples 5 through 9 as Examples 6 through 10;

■ h. In newly redesignated paragraph (g)(5), by adding a new Example 5;

■ i. In newly redesignated paragraph (g)(5), by revising newly redesignated Examples 6 through 10;

■ j. In newly redesignated paragraph (g)(5), by adding Example 11.

The revisions and additions read as follows:

§ 54.9815–1251 Preservation of right to maintain existing coverage.

* * * * *

(g) * * *

(1) * * * Subject to paragraphs (g)(2) and (3) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. * * *

* * * * *

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(4)(ii) of this section).

(iv) * * *

(A) An amount equal to $5 increased by medical inflation, as defined in paragraph (g)(4)(i) of this section (that is, $5 times medical inflation, plus $5), or

(B) The maximum percentage increase (as defined in paragraph (g)(4)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(4)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 54.9802(d)) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(4)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 54.9802(d)) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

* * * * *

(3) *Special rule for certain grandfathered high deductible health plans.* With respect to a grandfathered group health plan or group health insurance coverage that is a high deductible health plan within the meaning of section 223(c)(2), increases to fixed-amount cost-sharing requirements that otherwise would cause a loss of grandfather status will not cause the plan or coverage to relinquish its grandfather status, but only to the extent such increases are necessary to maintain its status as a high deductible health plan under section 223(c)(2)(A).

(4) * * *

(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means:

(A) With respect to increases for a group health plan and group health insurance coverage made effective on or after March 23, 2010, and before [the effective date of final rule], medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points; and

(B) With respect to increases for a group health plan and group health insurance coverage made effective on or after [effective date of final rule], the greater of:

(1) Medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points; or

(2) The portion of the premium adjustment percentage, as defined in 45 CFR 156.130(e), that reflects the relative change between 2013 and the calendar year prior to the effective date of the increase (that is, the premium adjustment percentage minus 1), expressed as a percentage, plus 15 percentage points.

* * * * *

(5) * * *

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment requirement of $30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to $40, effective before [effective date of final rule]. Within the 12-month period before the $40 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3,* the increase in the copayment from $30 to $40, expressed as a percentage, is 33.33% (40 − 30 = 10; 10 ÷ 30 = 0.3333; 0.3333 = 33.33%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2269 (475 − 387.142 = 87.858; 87.858 ÷ 387.142 = 0.2269). The maximum percentage increase permitted is 37.69% (0.2269 = 22.69%; 22.69% + 15% = 37.69%). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3,* except the grandfathered group health plan subsequently increases the $40 copayment requirement to $45 for a later plan year, effective before [effective date of final rule]. Within the 12-month period before the $45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4,* the increase in the copayment from $30 (the copayment that was in effect on March 23, 2010) to $45, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2527 (485 − 387.142 = 97.858; 97.858 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 (5 × 0.2527 = $1.26; $1.26 + $5 = $6.26). Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* Same facts as *Example 4,* except the grandfathered group health plan increases the copayment requirement to $45, effective *after* [effective date of final rule]. The greatest value of the overall medical care component of the CPI–U (unadjusted) in the preceding 12-month period is still 485. In the calendar year that includes the effective date of the increase, the applicable portion of the premium adjustment percentage is 36%.

(ii) *Conclusion.* In this *Example 5,* the grandfathered health plan may increase the copayment by the greater of: Medical inflation, expressed as a percentage, plus 15 percentage points; or the applicable portion of the premium adjustment percentage for the calendar year that includes the effective date of the increase, plus 15 percentage points. The latter amount is greater because it results in a 51% maximum percentage increase (36% + 15% = 51%) and, as demonstrated in *Example 4,* determining the maximum percentage increase using medical inflation yields a result of 40.27%. The increase in the copayment, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Because the 50% increase in the copayment is less than the 51% maximum percentage increase, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 6. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment of $10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to $15, effective before [effective date of final rule]. Within the 12-month period before the $15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 6,* the increase in the copayment, expressed as a percentage, is 50% (15 − 10 = 5; 5 ÷ 10 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a group plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% (0.0720 = 7.20%; 7.20% + 15% = 22.20%), or $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 6* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to $5.36.

Example 7. (i) *Facts.* The same facts as *Example 6,* except on March 23, 2010, the grandfathered health plan has no copayment ($0) for office visits for primary care providers. The plan is

subsequently, amended to increase the copayment requirement to $5, effective before [effective date of final rule].

(ii) *Conclusion.* In this *Example 7,* medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 7* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of $5.36. Thus, the $5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 8,* the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 9. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $5,000 for self-only coverage and $12,000 for family coverage. The required employee contribution for the coverage is $1,000 for self-only coverage and $4,000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ((5,000 − 1,000)/5,000) for self-only coverage and 67% ((12,000 − 4,000)/12,000) for family coverage. For a subsequent plan year, the COBRA premium is $6,000 for self-only coverage and $15,000 for family coverage. The employee contributions for that plan year are $1,200 for self-only coverage and $5,000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ((6,000 − 1,200)/6,000) for self-only coverage and 67% ((15,000 − 5,000)/15,000) for family coverage.

(ii) *Conclusion.* In this *Example 9,* because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125.

Example 10. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) *Conclusion.* In this *Example 10,* the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

Example 11. (i) *Facts.* A group health plan that is a grandfathered health plan and also a high deductible health plan within the meaning of section 223(c)(2) had a $2,400 deductible for family coverage on March 23, 2010. The plan is subsequently amended after [effective date of final rule] to increase the deductible limit by the amount that is necessary to comply with the requirements for a plan to qualify as a high deductible health plan under section 223(c)(2)(A), but that exceeds the maximum percentage increase.

(ii) *Conclusion.* In this *Example 11,* the increase in the deductible at that time does not cause the plan to cease to be a grandfathered health plan because the increase was necessary for the plan to continue to satisfy the definition of a high deductible health plan under section 223(c)(2)(A).

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Accordingly, the Department of Labor proposes to amend 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS.

■ 3. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 4. Amend § 2590.715–1251:

■ a. By revising the first sentence of paragraph (g)(1) introductory text;
■ b. By revising paragraphs (g)(1)(iii), (g)(1)(iv)(A) and (B), and (g)(1)(v);
■ c. By redesignating paragraphs (g)(3) and (4) as paragraphs (g)(4) and (5);
■ d. By adding a new paragraph (g)(3);
■ e. By revising newly redesignated paragraphs (g)(4)(i) and (ii);
■ f. In newly redesignated paragraph (g)(5), by revising Examples 3 and 4;
■ g. In newly redesignated paragraph (g)(5), by redesignating Examples 5 through 9 as Examples 6 through 10;
■ h. In newly redesignated paragraph (g)(5), by adding a new Example 5;
■ i. In newly redesignated paragraph (g)(5), by revising newly redesignated Examples 6 through 10;
■ j. In newly redesignated paragraph (g)(5), by adding Example 11.

The revisions and additions read as follows:

§ 2590.715–1251 Preservation of right to maintain existing coverage.

* * * * *

(g) * * *

(1) * * * Subject to paragraphs (g)(2) and (3) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. * * *

* * * * *

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(4)(ii) of this section).

(iv) * * *

(A) An amount equal to $5 increased by medical inflation, as defined in paragraph (g)(4)(i) of this section (that is, $5 times medical inflation, plus $5), or

(B) The maximum percentage increase (as defined in paragraph (g)(4)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution

rate based on cost of coverage (as defined in paragraph (g)(4)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 2590.702(d)) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(4)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 2590.702(d)) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

* * * * *

(3) *Special rule for certain grandfathered high deductible health plans.* With respect to a grandfathered group health plan or group health insurance coverage that is a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, increases to fixed-amount cost-sharing requirements that otherwise would cause a loss of grandfather status will not cause the plan or coverage to relinquish its grandfather status, but only to the extent such increases are necessary to maintain its status as a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code.

(4) * * *

(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means:

(A) With respect to increases for a group health plan and group health insurance coverage made effective on or after March 23, 2010, and before [the effective date of final rule], medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points; and

(B) With respect to increases for a group health plan and group health insurance coverage made effective on or after [effective date of final rule], the greater of:

(*1*) Medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points; or

(*2*) The portion of the premium adjustment percentage, as defined in 45 CFR 156.130(e), that reflects the relative change between 2013 and the calendar year prior to the effective date of the increase (that is, the premium adjustment percentage minus 1), expressed as a percentage, plus 15 percentage points.

* * * * *

(5) * * *

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment requirement of $30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to $40, effective before [effective date of final rule]. Within the 12-month period before the $40 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3,* the increase in the copayment from $30 to $40, expressed as a percentage, is 33.33% (40 − 30 = 10; 10 ÷ 30 = 0.3333; 0.3333 = 33.33%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2269 (475 − 387.142 = 87.858; 87.858 ÷ 387.142 = 0.2269). The maximum percentage increase permitted is 37.69% (0.2269 = 22.69%; 22.69% + 15% = 37.69%). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3,* except the grandfathered group health plan subsequently increases the $40 copayment requirement to $45 for a later plan year, effective before [effective date of final rule]. Within the 12-month period before the $45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4,* the increase in the copayment from $30 (the copayment that was in effect on March 23, 2010) to $45, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2527 (485 − 387.142 = 97.858; 97.858 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 (5 × 0.2527 = $1.26; $1.26 + $5 = $6.26). Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* Same facts as *Example 4,* except the grandfathered group health plan increases the copayment requirement to $45, effective *after* [effective date of final rule]. The greatest value of the overall medical care component of the CPI–U (unadjusted) in the preceding 12-month period is still 485. In the calendar year that includes the effective date of the increase, the applicable portion of the premium adjustment percentage is 36%.

(ii) *Conclusion.* In this *Example 5,* the grandfathered health plan may increase the copayment by the greater of: Medical inflation, expressed as a percentage, plus 15 percentage points; or the applicable portion of the premium adjustment percentage for the calendar year that includes the effective date of the increase, plus 15 percentage points. The latter amount is greater because it results in a 51% maximum percentage increase (36% + 15% = 51%) and, as demonstrated in *Example 4,* determining the maximum percentage increase using medical inflation yields a result of 40.27%. The increase in the copayment, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Because the 50% increase in the copayment is less than the 51% maximum percentage increase, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 6. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment of $10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to $15, effective before [effective date of final rule]. Within the 12-month period before the $15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 6,* the increase in the copayment, expressed as

a percentage, is 50% (15 − 10 = 5; 5 ÷ 10 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a group plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% (0.0720 = 7.20%; 7.20% + 15% = 22.20%), or $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 6* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to $5.36.

Example 7. (i) *Facts.* The same facts as *Example 6,* except on March 23, 2010, the grandfathered health plan has no copayment ($0) for office visits for primary care providers. The plan is subsequently, amended to increase the copayment requirement to $5, effective before [effective date of final rule].

(ii) *Conclusion.* In this *Example 7,* medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 7* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of $5.36. Thus, the $5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 8,* the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 9. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $5,000 for self-only coverage and $12,000 for family coverage. The required employee contribution for the coverage is $1,000 for self-only coverage and $4,000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ((5,000 − 1,000)/5,000) for self-only coverage and 67% ((12,000 − 4,000)/12,000) for family coverage. For a subsequent plan year, the COBRA premium is $6,000 for self-only coverage and $15,000 for family coverage. The employee contributions for that plan year are $1,200 for self-only coverage and $5,000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ((6,000 − 1,200)/6,000) for self-only coverage and 67% ((15,000 − 5,000)/15,000) for family coverage.

(ii) *Conclusion.* In this *Example 9,* because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 10. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) *Conclusion.* In this *Example 10,* the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

Example 11. (i) *Facts.* A group health plan that is a grandfathered health plan and also a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code had a $2,400 deductible for family coverage on March 23, 2010. The plan is subsequently amended after [effective date of final rule] to increase the deductible limit by the amount that is necessary to comply with the requirements for a plan to qualify as a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code, but that exceeds the maximum percentage increase.

(ii) *Conclusion.* In this *Example 11,* the increase in the deductible at that time does not cause the plan to cease to be a grandfathered health plan because the increase was necessary for the plan to continue to satisfy the definition of a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 147 as set forth below:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 5. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 6. Section 147.140 is amended:
■ a. By revising the first sentence of paragraph (g)(1) introductory text;
■ b. By revising paragraphs (g)(1)(iii), (g)(1)(iv)(A) and (B), and (g)(1)(v);
■ c. By redesignating paragraphs (g)(3) and (4) as paragraphs (g)(4) and (5);
■ d. By adding a new paragraph (g)(3);
■ e. By revising newly redesignated paragraphs (g)(4)(i) and (ii);
■ f. In newly redesignated paragraph (g)(5), by revising Examples 3 and 4;
■ g. In newly redesignated paragraph (g)(5), by redesignating Examples 5 through 9 as Examples 6 through 10;
■ h. In newly redesignated paragraph (g)(5), by adding a new Example 5;
■ i. In newly redesignated paragraph (g)(5), by revising newly redesignated Examples 6 through 10; and
■ j. In newly redesignated paragraph (g)(5), by adding Example 11.

The revisions and additions read as follows:

§ 147.140 Preservation of right to maintain existing coverage.

* * * * *

(g) * * *

(1) * * * Subject to paragraphs (g)(2) and (3) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. * * *

* * * * *

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage

increase (as defined in paragraph (g)(4)(ii) of this section).

(iv) * * *

(A) An amount equal to $5 increased by medical inflation, as defined in paragraph (g)(4)(i) of this section (that is, $5 times medical inflation, plus $5), or

(B) The maximum percentage increase (as defined in paragraph (g)(4)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(4)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 146.121(d) of this subchapter) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(4)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 146.121(d) of this subchapter) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

* * * * *

(3) *Special rule for certain grandfathered high deductible health plans.* With respect to a grandfathered group health plan or group health insurance coverage that is a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, increases to fixed-amount cost-sharing requirements that otherwise would cause a loss of grandfather status will not cause the plan or coverage to relinquish its grandfather status, but only to the extent such increases are necessary to maintain its status as a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code.

(4) * * *

(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means:

(A) With respect to increases for a group health plan and group health insurance coverage made effective on or after March 23, 2010, and before [the effective date of final rule], medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points;

(B) With respect to increases for a group health plan and group health insurance coverage made effective on or after [effective date of final rule], the greater of:

(*1*) Medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points; or

(*2*) The portion of the premium adjustment percentage, as defined in § 156.130(e) of this subchapter, that reflects the relative change between 2013 and the calendar year prior to the effective date of the increase (that is, the premium adjustment percentage minus 1), expressed as a percentage, plus 15 percentage points; and

(C) With respect to increases for individual health insurance coverage, medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points.

* * * * *

(5) * * *

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment requirement of $30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to $40, effective before [effective date of final rule]. Within the 12-month period before the $40 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3,* the increase in the copayment from $30 to $40, expressed as a percentage, is 33.33% (40 − 30 = 10; 10 ÷ 30 = 0.3333; 0.3333 = 33.33%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2269 (475 − 387.142 = 87.858; 87.858 ÷ 387.142 = 0.2269). The maximum percentage increase permitted is 37.69% (0.2269 = 22.69%; 22.69% + 15% = 37.69%). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3,* except the grandfathered group health plan subsequently increases the $40 copayment requirement to $45 for a later plan year, effective before [effective date of final rule]. Within the 12-month period before the $45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4,* the increase in the copayment from $30 (the copayment that was in effect on March 23, 2010) to $45, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2527 (485 − 387.142 = 97.858; 97.858 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 (5 × 0.2527 = $1.26; $1.26 + $5 = $6.26). Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* Same facts as *Example 4,* except the grandfathered group health plan increases the copayment requirement to $45, effective *after* [effective date of final rule]. The greatest value of the overall medical care component of the CPI–U (unadjusted) in the preceding 12-month period is still 485. In the calendar year that includes the effective date of the increase, the applicable portion of the premium adjustment percentage is 36%.

(ii) *Conclusion.* In this *Example 5,* the grandfathered health plan may increase the copayment by the greater of: Medical inflation, expressed as a percentage, plus 15 percentage points; or the applicable portion of the premium adjustment percentage for the calendar year that includes the effective date of the increase, plus 15 percentage points. The latter amount is greater because it results in a 51% maximum

percentage increase (36% + 15% = 51%) and, as demonstrated in *Example 4,* determining the maximum percentage increase using medical inflation yields a result of 40.27%. The increase in the copayment, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Because the 50% increase in the copayment is less than the 51% maximum percentage increase, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 6. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment of $10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to $15, effective before [effective date of final rule]. Within the 12-month period before the $15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 6,* the increase in the copayment, expressed as a percentage, is 50% (15 − 10 = 5; 5 ÷ 10 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a group plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% (0.0720 = 7.20%; 7.20% + 15% = 22.20%), or $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 6* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to $5.36.

Example 7. (i) *Facts.* The same facts as *Example 6,* except on March 23, 2010, the grandfathered health plan has no copayment ($0) for office visits for primary care providers. The plan is subsequently, amended to increase the copayment requirement to $5, effective before [effective date of final rule].

(ii) *Conclusion.* In this *Example 7,* medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 7* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of $5.36. Thus, the $5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 8,* the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 9. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $5,000 for self-only coverage and $12,000 for family coverage. The required employee contribution for the coverage is $1,000 for self-only coverage and $4,000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ((5,000 − 1,000)/5,000) for self-only coverage and 67% ((12,000 − 4,000)/12,000) for family coverage. For a subsequent plan year, the COBRA premium is $6,000 for self-only coverage and $15,000 for family coverage. The employee contributions for that plan year are $1,200 for self-only coverage and $5,000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ((6,000 − 1,200)/6,000) for self-only coverage and 67% ((15,000 − 5,000)/15,000) for family coverage.

(ii) *Conclusion.* In this *Example 9,* because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 10. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) *Conclusion.* In this *Example 10,* the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

Example 11. (i) *Facts.* A group health plan that is a grandfathered health plan and also a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code had a $2,400 deductible for family coverage on March 23, 2010. The plan is subsequently amended after [effective date of final rule] to increase the deductible limit by the amount that is necessary to comply with the requirements for a plan to qualify as a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code, but that exceeds the maximum percentage increase.

(ii) *Conclusion.* In this *Example 11,* the increase in the deductible at that time does not cause the plan to cease to be a grandfathered health plan because the increase was necessary for the plan to continue to satisfy the definition of a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2019–0720; FRL–10010–30–Region 2]

Approval of Source-Specific Air Quality Implementation Plans; New Jersey

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the State of New Jersey's State Implementation Plan (SIP) for the ozone National Ambient Air Quality Standard (NAAQS) related to a source-specific SIP for CMC Steel New Jersey, located at 1 N. Crossman, Sayreville, New Jersey (Facility). The control options in this source-specific SIP address volatile organic compounds (VOC) and nitrogen oxide (NO_X) Reasonably Available Control Technology (RACT) for the Facility's electric arc furnace (Sayreville EAF). The intended effect of this source-specific SIP revision is to allow the Facility to continue to operate under the current, New Jersey Department of Environmental Protection (NJDEP)

approved VOC and NO_X emission limits for the Sayreville EAF. The Facility met the statutory criteria and deadline to qualify for continuing to operate under its existing VOC and NO_X emission limits. This action will not increase the hourly emissions of the Sayreville EAF affected source and will not interfere with any applicable requirements of any National Ambient Air Quality Standard. Therefore, this action meets all applicable requirements of the Clean Air Act.

DATES: Comments must be received on or before August 14, 2020.

ADDRESSES: Submit your comments, identified by Docket Number EPA–R02–OAR–2019–0720, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, such as the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Linda Longo, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–3565, or by email at *longo.linda@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

The EPA proposes to approve a revision to the State of New Jersey's SIP for attainment and maintenance of the ozone NAAQS. Specifically, this action applies to the regulations under New Jersey Administrative Code (NJAC), Title 7, Chapter 27, Subchapter 16, ''Control and Prohibition of Air Pollution from Volatile Organic Compounds'' (NJAC 7:27–16) and New Jersey Administrative Code, Title 7, Chapter 27, Subchapter 19, ''Control and Prohibition of Air Pollution from Oxides of Nitrogen'' (NJAC 7:27–19). The NJDEP reviewed and approved the facility-specific emission limits for VOC and NO_X control plans as well as the associated RACT for the Sayreville EAF operated by the Facility. The two associated facility-specific emission limits for VOC and NO_X are the lowest emission limits with the application of control technology that are reasonably available given the technological and economic feasibility considerations associated with the Sayreville EAF.

CMC Steel New Jersey submitted this source-specific SIP revision requesting authorization to continue to operate under its current approved emission limits—specifically, the VOC emission rate of 57 pounds per hour (lb/hr) and the NO_X emission rate of 31 lb/hr—for the Sayreville EAF. A full summary of EPA's findings for this source-specific SIP revision is included in the technical support document (TSD) that is contained in EPA's docket assigned to this **Federal Register** document.

Ozone Requirements

On March 6, 2015, the EPA established a final rule for implementing the 2008 ozone NAAQS that repealed the 1997 ozone NAAQS and added anti-backsliding requirements to help smooth the transition between the 1997 and the 2008 ozone NAAQS for nonattainment areas. *See* 80 FR 12264 (March 6, 2015). In 1997, the EPA revised the health-based NAAQS for 8-hour ozone, setting it at 0.084 parts per million (ppm) averaged over an 8-hour time frame. *See* 62 FR 38856 (July 18, 1997). In March 2008, the EPA revised the 8-hour ozone NAAQS to 0.075 ppm (2008 ozone NAAQS), and in October 2015, to 0.070 ppm (2015 ozone NAAQS) while retaining the 2008 ozone indicators. *See* 73 FR 16436 (March 27, 2008); 80 FR 65292 (October 26, 2015). Under the Clean Air Act (CAA), after the EPA establishes a new or revised NAAQS, the EPA and the states must take steps to ensure that the new or revised NAAQS are met. One of the first steps, known as the ''initial area designations,'' involves identifying areas of the country that are not meeting the new or revised NAAQS, as well as the nearby areas that contain emission sources that contribute emissions to the areas' not meeting the NAAQS. On June 4, 2018, the EPA finalized its attainment/nonattainment designations for most areas across the country with respect to the 2015 8-hour ozone NAAQS. *See* 83 FR 25776 (June 4, 2018). The 2015 ozone NAAQS became effective on August 3, 2018.

The State of New Jersey encompasses two 2008 ozone NAAQS nonattainment areas: the Philadelphia-Wilmington-Atlantic City (PA–NJ–MD–DE), which is classified as marginal; and the New York-Northern New Jersey-Long Island (NY–NJ–CT) also referred to as the New York Metropolitan Area (NYMA), which has been reclassified as serious.[1] The New Jersey portion of the NYMA is made up of 12 counties: Bergen, Essex, Hudson, Hunterdon, Middlesex, Monmouth, Morris, Passaic, Somerset, Sussex, Union and Warren counties. CMC Steel New Jersey is located in Middlesex County.

On May 4, 2016, the EPA determined that the NYMA failed to attain the 2008 ozone NAAQS by the applicable marginal attainment date of July 20, 2015, and therefore the NYMA was reclassified from ''marginal'' to ''moderate'' nonattainment. *See* 81 FR 26697 (May 4, 2016).[2] As an area that is reclassified to a higher nonattainment classification, the NYMA was required to demonstrate attainment of the 2008 ozone NAAQS by the applicable attainment date of July 20, 2018; however, the NYMA again failed to meet the attainment date. Consequently, on August 23, 2019, the EPA reclassified the NYMA to ''serious'' nonattainment. CAA sections 172(c)(1), 182(b)(2) and 182(f) require nonattainment areas that are designated as ''moderate'' or above to adopt RACT.

RACT Requirements

RACT is defined as the lowest emission limit that a source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility.[3] The RACT analysis requires

[1] Determinations of Attainment by Attainment Date, Extensions of the Attainment Date, and Reclassifications of Several Areas Classified as Moderate for the 2008 Ozone National Ambient Air Quality Standards, *https://www.federalregister.gov/documents/2019/08/23/2019-17796/determinations-of-attainment-by-the-attainment-date-extensions-of-the-attainment-date-and.*

[2] Determinations of Attainment by Attainment Date, Extensions of the Attainment Date, and Reclassifications of Several Areas for the 2008 Ozone National Ambient Air Quality Standards, *https://www.federalregister.gov/documents/2016/05/04/2016-09729/determinations-of-attainment-by-the-attainment-date-extensions-of-the-attainment-date-and.*

[3] The EPA has not generally prescribed RACT requirements. As defined in ''State Implementation Plans; General Preamble for Proposed Rulemaking on Approval of Plan Revisions for Nonattainment

a two-step process. In the first step, the facility must identify control options that it does not currently implement but that are technologically feasible given its operations. In the second step, the facility must determine which of the identified control options is cost effective given its operational needs. The control options that are demonstrated as both technologically feasible and cost-effective are considered RACT.

The entire State of New Jersey is subject to RACT because: (1) The State is under the nonattainment area designations for the 8-hour ozone NAAQS (40 CFR 81.331), and (2) the State of New Jersey is located within the Ozone Transport Region (OTR), a region in which the CAA requires that state SIPs implement RACT requirements. *See* CAA § 184(b)(1)(B). Under the EPA guidelines (the ''Phase 2 Rule''), in RACT determinations, states should consider technologies that achieve 30–50 percent reduction within a cost range of $160–1300 per ton of NO_X removed. *See* 70 FR 71612 (November 29, 2005). On August 1, 2007, the NJDEP finalized RACT revisions to its SIP to address the 8-hour ozone NAAQS, and the EPA approved these revisions on May 15, 2009. *See* ''RACT for the 8-hour Ozone NAAQS and other Associated SIP Revisions for the Fine Particulate Matter, Regional Haze, and Transport of Air Pollution,'' available at *http://www.nj.gov/dep/baqp/sip/8-hrRACT-Final.pdf* and *see* 74 FR 22837 (May 15, 2009). The NJDEP, taking a more stringent approach, determined that control options with significantly higher costs than those discussed in the Phase 2 Rule would be considered reasonable under the State's RACT analysis. New Jersey's RACT rule does not suggest a dollar amount, but the NJDEP has identified a five-factor analysis for determining whether a control option constitutes RACT:

(1) Past New Jersey costs for retrofitting a given control;

(2) Average RACT cost (dollars per tons reduced) for a control technology and maximum RACT cost. Once a reasonable number of sources in a source category achieve a lower emission level, other sources should do the same;

(3) The seriousness of the Region's ozone air quality exceedance. For nonattainment areas with higher ozone levels, higher costs for controls are reasonable;

(4) The seriousness of the need to reduce transported air pollution. As an OTR state, higher costs for RACT are justified; and

(5) The NJDEP plan for addressing economic feasibility in RACT rules.

The NJDEP intended to specify RACT at the lowest emission limit that a reasonable number of facilities that are similar to the source under consideration had already successfully implemented for each source category.

II. The EPA's Evaluation of New Jersey's Submittals

In accordance with NJAC 7:27–16.17 and NJAC 7:27–19, NJDEP requested [4] for CMC Steel New Jersey to submit updated facility-specific VOC and NO_X control plans so that the State could determine whether new emission control options for the electric arc furnace had emerged since the Facility's last submission and NJDEP approval in 2009. In response, CMC Steel New Jersey submitted to NJDEP the facility-specific VOC and NO_X control plans that are the subject of this source-specific SIP revision. In a letter from NJDEP Commissioner Catherine R. McCabe to the U.S. EPA Region 2 Regional Administrator Peter D. Lopez (dated April 30, 2019), NJDEP requested the EPA's approval of the current revision to the New Jersey SIP for the ozone NAAQS to incorporate CMC Steel New Jersey's facility-specific control plans.

NJDEP's current source-specific SIP revision requests that the EPA evaluate the RACT analysis which would set CMC Steel New Jersey's facility-specific VOC emission rate at 57 lb/hr and its facility-specific maximum allowable NO_X emission rate at 31 lb/hr. The Operating Permit contains a maximum potential to emit (PTE) of 78.7 tons per year (TPY) of VOC and maximum PTE of 78.8 TPY of NO_X for the Sayreville EAF.[5] According to the most recent facility emissions inventory, other sources of VOC and NO_X emissions at the Facility's melt shop include: a scrap pre-heater, three ladle preheaters, a tundish preheater, and billet cutting torches; each of these enumerated sources contributes well less than 3 lb/hr of VOC emissions and less than 1 TPY of NO_X to the overall VOC and NO_X emissions from the Facility. Therefore, only the Sayreville EAF source operation is subject to the VOC RACT rule and the NO_X RACT rule as set forth in NJAC 7:27–16.17 and NJAC 7:27–19.13, respectively.

The EPA reviewed the NJDEP's April 30, 2019, source-specific SIP revision submittal, which includes the CMC Steel New Jersey RACT analysis, for completeness and approvability. The EPA review included: studying various EPA RACT technical guidance documents, an evaluation of comparable electric arc furnace emission control technologies deployed at facilities nationwide, and consultation with air pollution control experts from the NJDEP and the EPA. Details of the EPA's review are included in the TSD contained in this docket.

Qualifying To Continue To Operate Under Current Approved Emission Limits

The CMC Steel New Jersey VOC and NO_X control plans identify the proposed emission limits for the Sayreville EAF. The Facility met NJDEP's statutory criteria and deadline to qualify for continuing to operate under existing VOC and NO_X emission limits. Under NJAC: 7:27–16.17(c)(3), facilities that sought to continue operating with an alternative VOC control plan that was approved prior to May 19, 2009, were required to submit updated proposed VOC control plans to NJDEP for review by August 17, 2009. The initial facility-specific VOC RACT plan for the Sayreville EAF was approved in October 1994, and on August 17, 2009 the Facility timely submitted a revised VOC RACT plan with a VOC emission rate of 57 lb/hr. Similarly, under NJAC: 7:27–19.13(a)(3), facilities that sought to continue to operate under existing NO_X control plans that were approved prior to May 1, 2005, were required to submit updated proposed NO_X control plans to NJDEP for review by August 17, 2009. The initial facility-specific NO_X RACT plan for the Sayreville EAF was approved in May 1995, and on August 17, 2009 the Facility timely submitted a revised NO_X RACT plan with a facility-specific maximum allowable NO_X emission rate of 31 lb/hr.

RACT Analysis

The Facility's RACT analysis identifies seven VOC control

Areas—Supplement (on Control Techniques Guidelines),'' RACT for a source is determined on a case-by-case basis, considering the technological and economic circumstances of the individual source. *See* 44 FR 53761 September 17, 1979.

[4] By email correspondence (dated September 7, 2018), NJDEP requested Gerdau Ameristeel (the former owner of the Facility) to submit updated facility-specific VOC and NO_X control plans, because under NJAC 7:27–16.17 and NJAC 7:27–19, respectively, such plans have terms of 10 years. Having been approved in about 2009, the CMC Steel New Jersey's facility-specific control plans under the referenced provisions were near expiration. Note that on December 5, 2018, the NJDEP approved an administrative amendment to the Facility's CAA Title V operating permit to reflect the change in ownership and name from Gerdau Ameristeel to CMC Steel New Jersey. All control options and operating permit limits for the Sayreville EAF remain the same for the new owner CMC Steel New Jersey.

[5] The electric arc furnace is situated in the Facility's melt shop.

technologies and eight NO_X control technologies for a typical electric arc furnace. Three control technologies are currently being implemented at the Sayreville EAF (two VOC and one NO_X controls) and one VOC control technology (*i.e.,* a thermal incinerator) was considered technologically feasible but not currently implemented.

The VOC controls currently implemented at the Sayreville EAF are: Operating in accordance with the Facility's Scrap Management Plan with which the Facility achieves reduced VOC emissions by ensuring that purchased scrap material are of a consistent and verifiable quality to minimize the amount of nonmetallic/organic material (such as oil, grease, and plastic) that could result in VOC emissions when heated; and a direct evacuation system (DES) which destroys[6] VOC emissions. The VOC control technologies that are not technologically feasible for the Sayreville EAF are: Catalytic incineration; flares; mixed bed carbon adsorption; and condensers/recapture systems.

The NO_X control currently implemented by the Sayreville EAF is good operating practices, through which the Facility maintains a constant temperature in the preheater chamber (which feeds scrap metal to the EAF) so that scrap metal is melted before it enters the Sayreville EAF thereby avoiding temperature spikes that could generate greater NO_X emissions. The Facility's good operating practices also minimizes its electricity consumption which allows the Facility to avoid indirect NO_X emissions. The NO_X control technologies that are not technologically feasible for the Sayreville EAF are: DES; low NO_X/oxy-fuel burner; low excess air; flue gas recirculation/temperature reduction; selective catalytic reduction; selective non-catalytic reduction; and non-selective catalytic reduction.

The Facility conducted the RACT analysis on the thermal incinerator VOC control technology. The Facility demonstrated that VOC reductions from the thermal incinerator are not cost effective and therefore not RACT. Cost effectiveness is measured in dollars per ton of emissions reductions per year (*i.e.,* the cost per ton of pollutant controlled). The cost effectiveness analysis includes many factors, among which are: Consideration of process capital equipment, total plant cost and investment, fixed and variable operating cost, total capital requirement and consumable costs. Because sources vary in many important characteristics (including, among others, age, condition, and size), the actual cost, emission reduction, and cost effectiveness levels that an individual source experiences in meeting the RACT requirements also vary. Costs of meeting RACT also vary by the geographic locations of different sources as well as between emission units within a source. Rather than focusing on a single cost effectiveness figure for controls, EPA recommends that states consider a cost effectiveness range, because the actual cost effectiveness may vary. *See e.g.,* Memorandum from D. Kent Berry (dated March 16, 1994), ''Cost effective Nitrogen Oxides (NO_X) Reasonably Available Control Technology (RACT).''

Based on the November 2017 updates to the EPA Air Pollution Control Cost Manual, the maximum costs considered are for a 50,000 standard cubic feet per minute (SCFM) thermal incinerator. Although larger thermal incinerator units can be built, sources rarely use flow rates above 50,000 SCFM. Therefore, CMC Steel New Jersey calculated the cost needed to handle a flow rate of 100,000 SCFM based on the cost of two 50,000 SCFM units. The cost effectiveness of operating two thermal incinerators was calculated by dividing the total annual cost of two thermal incinerators ($3,647,283) by the amount of VOC emissions that would be removed (74.8 TPY). The VOC reduction was in turn calculated by multiplying the baseline of 78.7 TPY (the PTE from the Facility's Title V permit) by an assumed thermal incinerator control efficiency of 95-percent, which resulted in a reduction of 74.8 TPY of VOC. The 95-percent control efficiency was selected based on EPA guidance.[7] Furthermore, as explained in Section I above, under EPA rulemaking states should consider in their RACT determinations technologies that achieve 30–50 percent reduction within a cost range of $160–$1,300 per ton of NO_X removed.[8] The cost effectiveness of installing two thermal incinerators on the Sayreville EAF expressed in annual costs is $48,760 per ton VOC reduced. Therefore, NJDEP concluded that the thermal incinerator control technology is not to be RACT due to technological and economical infeasibility under federal and state RACT criteria.

The EPA agrees that thermal incineration technology is not cost effective and is not routinely implemented on electric arc furnaces. This technology's poor performance with electric arc furnaces possibly results from its unsuitability for applications where there are large fluctuations in flow rate or those in which reduced residence time and mixing during increased flow would result in lower destruction efficiency. EPA's review of the available literature reveals that while thermal incineration can handle minor flow rate fluctuations, the system cannot handle excessive flow rate fluctuations, which could require use of a flare. Thermal incinerators also have high fuel consumption demands and are better suited for small process operations, and not those found at the Facility. Finally, thermal incineration forms highly corrosive acid gases whose effects require the operation of post-oxidation acid gas treatment system. To remedy the problems associated with use of a thermal incineration system would add costs to the already high costs of operating thermal incineration units at the Facility.[9]

III. Proposed Action

The EPA finds that the current source-specific SIP revision is approvable because the Facility can meet emission limits set by NJDEP, implement RACT controls, and the Facility's application for facility-specific alternative control plans for VOC and NO_X meet the relevant regulatory requirements. First, based on a thorough review of similar sources, and an analysis of this source-specific SIP revision, the EPA proposes to allow CMC Steel New Jersey to continue to operate under the NJDEP-approved emission limits for the Sayreville EAF. Specifically, the EPA proposes to set the Facility's VOC emission rate at 57 lb/hr and the NO_X emission rate at 31 lb/hr. The EPA finds that no VOC and no NO_X controls other than those the Facility already has in place can be designated RACT. The VOC controls currently implemented at the Facility (*i.e.,* the DES and the Scrap Management Plan) allow the Facility to meet the 57 lb/hr VOC limit. For NO_X, the Facility will continue to implement the Best Management Practices to avoid temperature spikes and minimize electricity use which would allow the Facility to meet the 31 lb/hr NO_X limit. Second, the Facility's application meets the statutory requirement for facilities

[6] The DES helps destroy VOC emissions by sending the gas stream back through the high temperature preheater chamber.

[7] Handbook Control Technologies for Hazardous Air Pollutants, EPA/625/6–91/014, June 1991.

[8] As explained in the TSD, the NO_X Supplement applies to major stationary sources of NO_X the same as major stationary sources of VOC emissions.

[9] *See e.g.,* EPA Air Pollution Control Technology Fact Sheet, Technology: Thermal Incinerator, EPA 452/F–03–022, *https://nepis.epa.gov/Exe/ZyPDF.cgi/P100RQ6F.PDF?Dockey=P100RQ6F.PDF* (last accessed Mar. 19, 2020).

that seek to continue to operate under existing facility-specific control plans for VOC and NO_X. The Facility had existing facility-specific control plans that were approved prior to May 19, 2009 and submitted its facility-specific control plan by August 17, 2009, as required under NJAC 7:27–16.17(c)(3) for VOC and under NJAC 7:27–19.13(a)(3) for NO_X. As stated, the Facility underwent a change in ownership to CMC Steel New Jersey but made no changes to its equipment. As a result, the Facility is entitled to rely on its previously approved facility-specific control plans under both statutory provisions.

IV. Incorporation by Reference

In this document, we are proposing to include regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, we are proposing to incorporate by reference the provisions described above in Section III. Proposed Action.

The EPA has made, and will continue to make, these documents generally available electronically through *http://www.regulations.gov* and in hard copy at the appropriate EPA regional office, 290 Broadway, 25th floor, New York, New York, 10007–1866.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule does not have tribal implications as specified by Executive Order 13175, because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

List of Subjects 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compound.

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

Dated: June 30, 2020.

Peter Lopez,

Regional Administrator, Region 2.

[FR Doc. 2020–14632 Filed 7–14–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R03–OAR–2019–0527; FRL–10011–14–Region 3]

Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; State of Maryland; Control of Emissions From Existing Sewage Sludge Incineration Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the negative declaration submitted by the State of Maryland for Sewage Sludge Incineration (SSI) units. This negative declaration submitted by the Maryland Department of the Environment (MDE) certifies that SSI units subject to sections 111(d) and 129 of the Clean Air Act (CAA) do not exist within the jurisdiction of the State of Maryland. This action is being taken under the CAA.

DATES: Written comments must be received on or before August 14, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2019–0527 at *https://www.regulations.gov,* or via email to *Opila.MaryCate@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Matthew Willson, Permits Branch (3AD10), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–5795. Mr. Willson can also be reached via electronic mail at *Willson.Matthew@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The CAA requires that state regulatory agencies implement emission guidelines and associated compliance times using a state plan developed under sections 111(d) and 129 of the CAA. The general provisions for the submittal and approval of state plans are codified in 40 Code of Federal Regulations (CFR) part 60, subpart B and 40 CFR part 62, subpart A. Section 111(d) establishes general requirements and procedures on state plan submittals for the control of designated pollutants. Section 129 requires emission guidelines to be promulgated for all categories of solid waste incineration units, including SSI units. SSI units are defined at 40 CFR 60.5250 as ''an incineration unit combusting sewage sludge for the purpose of reducing the volume of the sewage sludge by removing combustible matter. Sewage sludge incineration unit designs include fluidized bed and multiple hearth. A SSI unit also includes, but is not limited to, the sewage sludge feed system, auxiliary fuel feed system, grate system, flue gas system, waste heat recovery equipment, if any, and bottom ash system. The SSI unit includes all ash handling systems connected to the bottom ash handling system. The combustion unit bottom ash system ends at the truck loading station or similar equipment that transfers the ash to final disposal. The SSI unit does not include air pollution control equipment or the stack.''

Section 129 mandates that all plan requirements be at least as protective as the promulgated emission guidelines. This includes fixed final compliance dates, fixed compliance schedules, and title V permitting requirements for all affected sources. Section 129 also requires that state plans be submitted to EPA within one year after EPA's promulgation of the emission guidelines and compliance times.

States have options other than submitting a state plan in order to fulfill their obligations under CAA sections 111(d) and 129. If a state does not have any existing SSI units for the relevant emission guidelines, a letter can be submitted certifying that no such units exist within the state (*i.e.,* negative declaration) in lieu of a state plan, in accordance with 40 CFR 60.5010. The negative declaration exempts the state from the requirements of subpart B that would otherwise require the submittal of a CAA section 111(d)/129 plan.

On March 21, 2011 (76 FR 15372), EPA finalized emission guidelines for SSI units at 40 CFR part 60, subpart MMMM. Following the 2011 final rule, MDE determined that there was one SSI facility in Maryland that met the applicability criteria for the Federal plan. On January 20, 2017, MDE submitted a letter to EPA requesting full delegation of authority to implement the SSI Federal plan. However, that facility has now permanently shut down and has relinquished its title V Permit to operate. Accordingly, MDE sent a negative declaration for SSI units on April 3, 2020.

For additional background information on MDE's negative declaration, see the documents that are available online at *https://www.regulations.gov,* Docket No. EPA–R03–OAR–2019–0527. EPA is proposing to approve MDE's negative declaration submission made on April 3, 2020. This action applies to the state's regulatory requirements for existing facilities and not new sources.

II. Proposed Action

In this proposed action, EPA proposes to amend 40 CFR part 62 to reflect receipt of the negative declaration letter from MDE certifying that there are no existing SSI units subject to 40 CFR part 60, subpart MMMM, in accordance with section 111(d) of the CAA. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

III. Statutory and Executive Order Reviews

EPA's role with regard to negative declarations for designated facilities received by EPA from states is to notify the public of the receipt of such negative declarations and revise 40 CFR part 62 accordingly. This action merely proposes to approve the state's negative declaration as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule, regarding the negative declaration of SSI units in Maryland, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because this action is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 62

Environmental protection, Air pollution control, Administrative practice and procedure, Sewage sludge incineration units.

Dated: June 25, 2020.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2020–14577 Filed 7–14–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1983–0002; FRL–10011–34–Region 1]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Industri-Plex Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 1 is issuing a Notice of Intent to Delete the 200 Presidential Way, Woburn, MA 01801 (200 Presidential Way) parcel of the Industri-Plex Superfund Site (Site) (MAD076580950) located in Woburn, Massachusetts, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the Commonwealth of Massachusetts, through the Massachusetts Department of Environmental Protection, have determined that all appropriate response actions at the identified parcel under CERCLA, been completed. However, this partial deletion does not preclude future actions under Superfund.

This partial deletion pertains to soil and groundwater at the approximately 10.7-acre 200 Presidential Way parcel. The remaining areas/media of the Industri-Plex Superfund Site will remain on the NPL and are not being considered for deletion as part of this action.

DATES: Comments must be received by August 14, 2020.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1983–0002, by one of the following methods:

- *http://www.regulations.gov.* Follow on-line instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*
- *Email: Lemay.Joe@epa.gov*.
- Written comments submitted by mail are temporarily suspended and no hand deliveries will be accepted. EPA encourage the public to submit comments via *https://www.regulations.gov*.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–1983–0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in at the EPA Region 1 SEMS Records and Information Center (SEMS RIC). Publicly available docket materials are available either electronically at: *http://www.regulations.gov, https://semspub.epa.gov/src/collection/01/AR66357* or *https://go.usa.gov/xvvr6*. EPA site specific web page: *www.epa.gov/superfund/industriplex*.

The EPA is temporarily suspending its Docket Center and Regional Records Centers for public visitors to reduce the risk of transmitting COVID–19. In addition, many site information repositories are closed and information in these repositories, including the deletion docket, has not been updated with hardcopy or electronic media. 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 Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID.

FOR FURTHER INFORMATION CONTACT: Joseph LeMay, Remedial Project Manager, U.S. Environmental Protection Agency, Region 1—New England, 5 Post Office Square, Suite 100 (mail code: 07–4), Boston, MA 02109–3912, (617) 918–1323, email: *Lemay.Joe@epa.gov*; or SEMS Records & Information Center, EPA Region 1—New England, 5 Post Office Square, Suite 100 (mail code: 02–3), Boston, MA 02109–3912, (617) 918–1440, email: *R1.Records-SEMS@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA Region 1—New England announces its intent to delete the soil and groundwater of the approximately 10.7-acre 200 Presidential Way, Woburn, MA, (200 Presidential Way) parcel of the Industri-Plex Superfund Site (Site), from the National Priorities List (NPL) and request public comment on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of

the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as those sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). This partial deletion of 200 Presidential Way parcel at the Site is proposed in accordance with 40 CFR 300.425(e) and is consistent with the Notice of Policy Change: Partial Deletion of Sites Listed on the National Priorities List. 60 FR 55466 (Nov. 1, 1995). As described in 300.425(e)(3) of the NCP, a portion of a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

EPA will accept comments on the proposal to partially delete this site for thirty (30) days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses where to access and review information that demonstrates how the deletion criteria have been met for the 200 Presidential Way parcel of the Industri-Plex Superfund site and demonstrates how the parcel meets the deletion criteria. Site.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the Commonwealth of Massachusetts, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. the remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

III. Deletion Procedures

The following procedures apply to deletion of 200 Presidential Way parcel of the Site:

(1) EPA consulted with the Commonwealth of Massachusetts before developing this Notice of Intent for Partial Deletion.

(2) EPA has provided the Commonwealth of Massachusetts 30 working days for review of this notice prior to publication of it today.

(3) In accordance with the criteria discussed above, EPA has determined that no further response is appropriate.

(4) The Commonwealth of Massachusetts, through the Massachusetts Department of Environmental Protections, has concurred with the deletion of the 200 Presidential Way parcel at the Industri-Plex Superfund Site, from the NPL.

(5) Concurrently, with the publication of this Notice of Intent for Partial Deletion in the **Federal Register**, a notice is being published in a major local newspaper, Woburn Times Chronicle. The newspaper announces the 30-day public comment period concerning the Notice of Intent for Partial Deletion of the Site from the NPL.

(6) The EPA placed copies of documents supporting the proposed partial deletion in the deletion docket, made these items available for public inspection, and copying at the Site information repositories identified above.

If comments are received within the 30-day comment period on this document, EPA will evaluate and respond accordingly to the comments before making a final decision to delete the 200 Presidential Way parcel of the Site. If necessary, EPA will prepare a Responsiveness Summary to address any significant public comments received. After the public comment period, if EPA determines it is still appropriate to delete the 200 Presidential Way parcel of the Site, the Regional Administrator will publish a final Notice of Partial Deletion in the **Federal Register**. Public notices, public submissions and copies of the Responsiveness Summary, if prepared, will be made available to interested parties and included in the site information repositories listed above.

Deletion of a portion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a portion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Partial Site Deletion

The EPA placed copies of documents supporting the proposed partial deletion in the deletion docket. The material supports EPA's rationale for the partial deletion of the 200 Presidential Way parcel at the Site. This information is made available for public inspection in the dockets identified above.

The Site boundary and approximate location of the 200 Presidential Way parcel are illustrated on Figure 1. The 200 Presidential Way parcel is approximately 10.7 acres, and the specific location of the parcel is illustrated on Figure 2. Soils and groundwater within the 200 Presidential Way parcel were included in Operable Unit 1 (OU–1) through a Record of Decision (ROD) issued by EPA in 1986. Final groundwater cleanup at the Industri-Plex Site was included in Operable Unit 2 (OU–2) through a ROD issued by EPA in 2006, where the Commonwealth of Massachusetts classified the groundwater within the 200 Presidential Way parcel as a non-drinking water aquifer. Prior to EPA issuing a June 2018 Explanation of Significant Difference (ESD) for OU–1 which modified the findings in the 1986 ROD pertaining to the 200 Presidential Way parcel, no remedial cleanup work had been conducted on the 200 Presidential Way parcel. Based on information provided in support of the 2018 ESD, EPA agreed that baseline risk assessment calculations for the evaluated soil and groundwater exposure scenarios do not exceed EPA's CERCLA risk management criteria, and that residential exposure to soils on the 200 Presidential Way parcel, residential exposure to groundwater associated with the vapor intrusion pathway and contact risk, and construction worker exposures to soil and groundwater were acceptable under CERCLA. Through the 2018 ESD, EPA determined that residential use, as well as daycare and school uses (with exposure similar to or less than residential use), of the 200 Presidential Way parcel was reasonable, and no further CERCLA restrictions needed to apply to the parcel to allow for unrestricted use/unrestricted exposure (UU/UE). Therefore, no CERCLA institutional control in the form of Notice of Activity and Use Limitation to notify future owners of CERCLA land use restrictions needs to be recorded on the 200 Presidential Way parcel.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste,

Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1251 *et seq.*

Dated: June 18, 2020.

Dennis Deziel,

Regional Administrator, EPA Region 1 New England.

BILLING CODE 6560–50–P

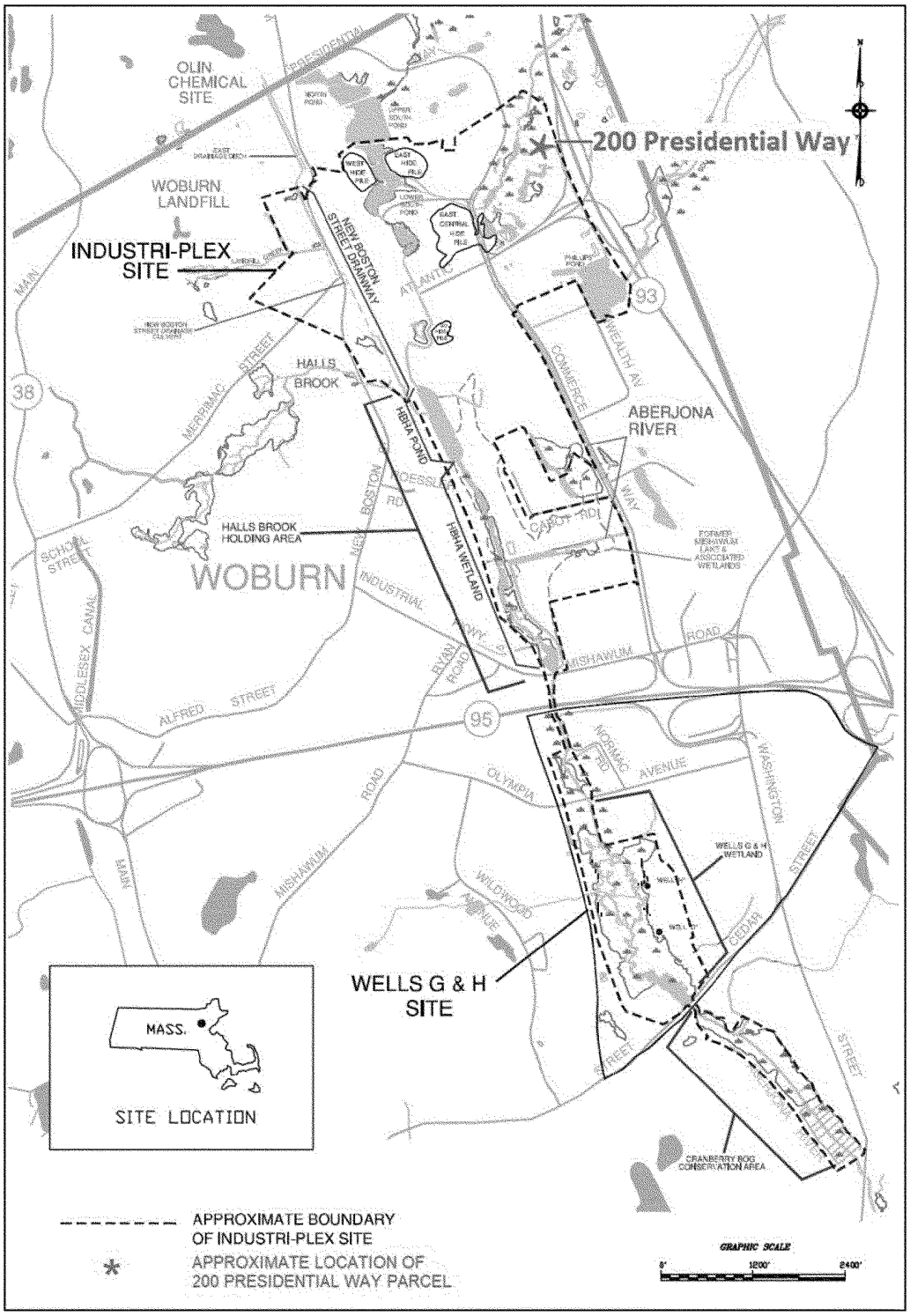
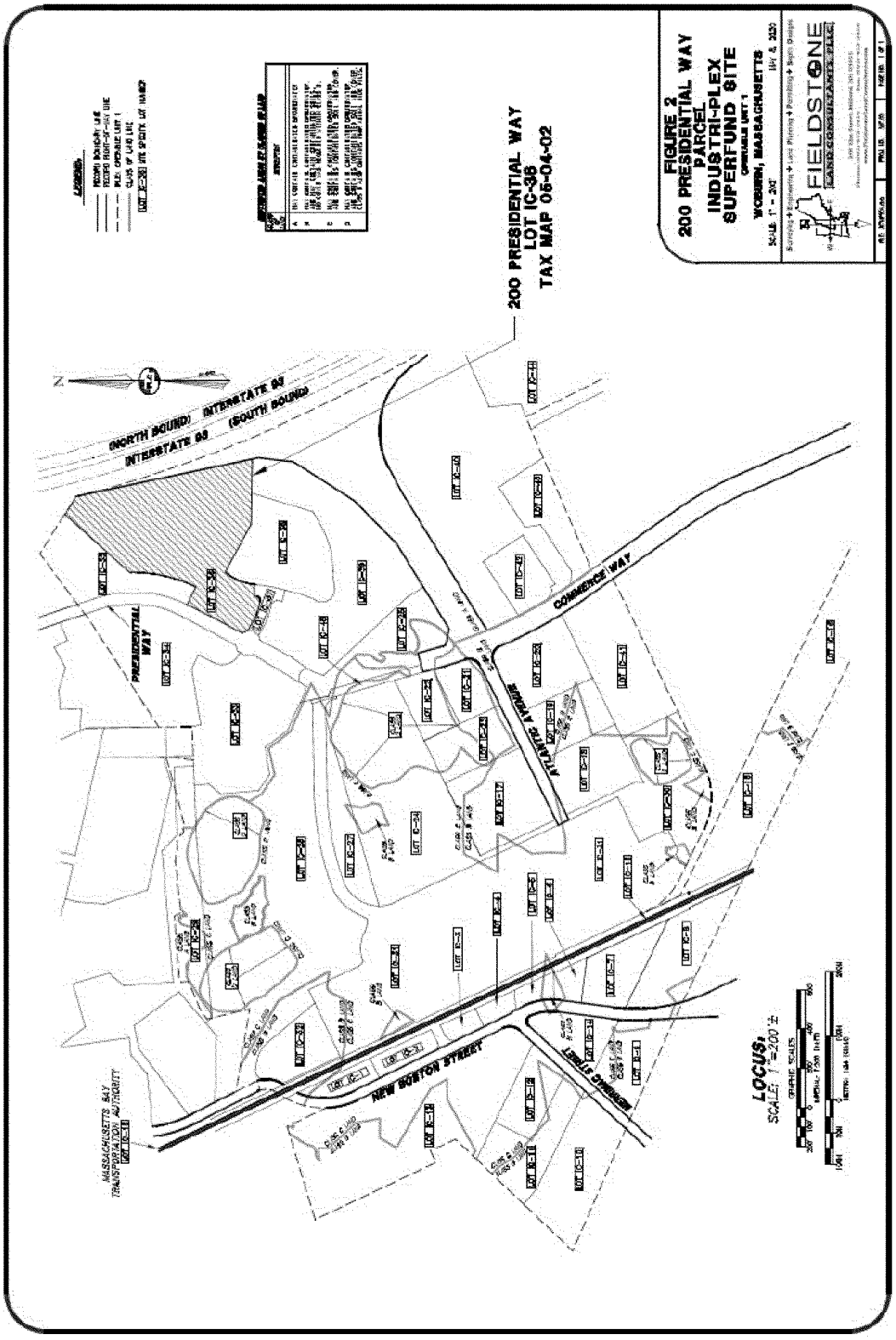


FIGURE 1
Locus of Industri-plex Site and 200 Presidential Way Parcel



[FR Doc. 2020–13637 Filed 7–14–20; 8:45 am]

BILLING CODE 6560–50–C

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2011–0066; FRL–10011–58–Region 4]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Red Panther Chemical Company Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 4 is issuing a Notice of Intent to Delete the Red Panther Chemical Company Superfund Site (Site) located in Clarksdale, Mississippi, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Mississippi, through the Mississippi Department of Environmental Quality (MDEQ), have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments must be received by August 14, 2020.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–2011–0066, by one of the following methods:

• ''*https://www.regulations.gov*'' *https://www.regulations.gov.* Follow on-line instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

• Following Centers for Disease Control and Prevention (CDC) and Office of Policy Management (OPM) guidance and specific state guidelines impacting our regional offices, the EPA's workforce has been authorized to telework to help prevent transmission of the coronavirus [COVID–19]. As a result, there is a temporary shutdown of the EPA's Docket Center and the EPA Regional Records Centers. While in this workforce telework status, there are practical limitations on the ability of staff to collect, and for Agency personnel to respond to, ''hard copy'' mailed queries sent directly to Agency office locations. Therefore, until the workforce is able to return to office locations, the EPA recommends that, to the extent feasible, any correspondence mailed to the Agency should also be sent via email.

• For question on this Notice and submission of comments please contact—Carter Owens, Remedial Project Manager, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW—MS9T25, Atlanta GA, 30303, (404) 562–8445, *owens.carter@epa.gov* or La'Tonya Spencer at *spencer.latonya@epa.gov.*

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–2011–0066. 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *https://www.regulations.gov* or email. The *https://www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to 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 disk or CD–ROM 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 avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available electronically at *https://www.regulations.gov.*

The EPA is temporarily suspending its Docket Center and Regional Records Centers for public visitors to reduce the risk of transmitting COVID–19. In addition, many site information repositories are closed and information in these repositories, including the deletion docket, has not been updated with hardcopy or electronic media. For further information and updates on the 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 Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19. The EPA is committed to continuing our critical work on behalf of the American public while also safeguarding the health and safety of the public and the families of the EPA employees by taking responsible measures to help prevent transmission of the coronavirus. Thank you for your cooperation and understanding.

FOR FURTHER INFORMATION CONTACT: Carter Owens, Remedial Project Manager, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, GA 30303, (404) 562–8445, email: *owens.carter@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The EPA Region 4 announces its intent to delete the Red Panther Chemical Company Superfund Site from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which the EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. The EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in 40 CFR 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions if future conditions warrant such actions.

The EPA will accept comments on the proposal to delete this site for thirty (30) days after publication of this document in the **Federal Register**.

Section II of this preamble explains the criteria for deleting sites from the NPL. Section III of this preamble discusses procedures that the EPA is using for this action. Section IV of this preamble discusses where to access and review information that demonstrates how the deletion criteria have been met at the Red Panther Chemical Company Superfund Site.

II. NPL Deletion Criteria

The NCP establishes the criteria that the EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), the EPA will consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. the remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

(1) The EPA consulted with the State before developing this Notice of Intent to Delete;

(2) The EPA has provided the state 30 working days for review of this action prior to publication of it today;

(3) In accordance with the criteria discussed above, the EPA has determined that no further response is appropriate;

(4) The State of Mississippi, through the Mississippi Department of Environmental Quality, has concurred with deletion of the Site from the NPL;

(5) Concurrently with the publication of this Notice of Intent to Delete in the **Federal Register**, a notice is being published in a major local newspaper, The Clarksdale Press Register Newspaper. The newspaper notice announces the 30-day public comment period concerning the Notice of Intent to Delete the Site from the NPL; and

(6) The EPA placed copies of documents supporting the proposed deletion in the deletion docket and made these items available for public inspection and copying at the site information repositories identified above.

If comments are received within the 30-day public comment period on this document, the EPA will evaluate and respond appropriately to the comments before making a final decision to delete. If necessary, the EPA will prepare a Responsiveness Summary to address any significant public comments received. After the public comment period, if the EPA determines it is still appropriate to delete the Site, the Regional Administrator will publish a final Notice of Deletion in the **Federal Register**. Public notices, public submissions and copies of the Responsiveness Summary, if prepared, will be made available to interested parties and in the site information repositories listed above.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist the EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Intended Site Deletion

The following information provides EPA's rationale for deleting the Site from the NPL:

Site Background and History

The Red Panther Chemical Company Site (CERCLIS ID: MSD000272385) is located in a mixed commercial-residential area of Clarksdale, Coahoma County, Mississippi. The Site area includes, but is not limited to, the 6.5-acre former Red Panther Facility (RPF) property, the 18th Street Neighborhood located to the west of the RPF, the vacant Industrial Parcel (IP) located south of the RPF, and the Storm Water Drainage Ditch Outfall located about 2,500 feet southwest of the RPF. The geographical coordinates of the RPF property are latitude 34°11′14.67″ North and longitude 90°33′41.85″ West. A pesticide formulation plant was operated at the RPF from 1949 to 1996. The plant formulated liquid and powdered herbicides, insecticides, and fungicides, including products containing toxaphene, aldrin, arsenic, dieldrin, and dichlorodiphenyltrichloroethane (DDT).

In 1999, the EPA conducted surface and subsurface soil sampling of the drainage ditches to the east of the property, the former onsite leaching field and septic tank, and the rail spur in front of the loading dock along the west side of the property. Samples were analyzed for metals and pesticides, and results indicated elevated levels of arsenic, organo-chlorine pesticides and their degradation by-products.

In September 2001, the EPA entered into an Administrative Settlement Agreement and Order on Consent (ASAOC) with the Site Potentially Responsible Party (PRP) group for a PRP-conducted removal action and additional characterization. The 2001 ASAOC identified the following constituents of concern (COCs) and set performance standards governing the removal action for surface and subsurface soils:

- *Surface Soil:* Arsenic, toxaphene, dieldrin, and total chlorinated pesticides. Performance standards were established for surface soil COCs at 39 ppm, 3 ppm, 23 ppm, and 100 ppm, respectively; and
- *Sub-surface Soil:* Arsenic, toxaphene, and dieldrin. Performance standards were established for sub-surface soil COCs at 220 ppm, 15 ppm, and 270 ppm, respectively.

Performance standards are not equivalent to remedial goals. Performance standards are developed as site-specific screening levels in accordance with the EPA's 1996 Soil Screening Guidance (SSG) and 2002 Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites. SSG is a tool developed by the

EPA to help standardize and accelerate the evaluation and cleanup of contaminated soils at sites on the NPL where future residential land use is anticipated. Generally, at sites where contaminant concentrations fall below screening levels, no further action or study is warranted under CERCLA.

In late 2002 and early 2003, surface soils, above the 2001 ASAOC performance standards, were excavated from the drainage ditches along the east side of the Site between the site property boundaries and Route 49 (Desoto Avenue). Approximately 825 tons of non-hazardous soils were disposed of off-site at the Waste Management Subtitle D landfill in Tunica Mississippi. Approximately 75 tons of hazardous soils were stockpiled onsite and secured. During the ditch remediation, additional soil characterization samples were collected from the Site. Samples collected from the northern portion of the Site had elevated levels of arsenic only and were not impacted by chlorinated pesticides. Samples collected along the railroad on the western portion of the Site had elevated levels of arsenic and chlorinated pesticides. Samples collected from the southern portion of the Site had lower levels of arsenic, but elevated levels of chlorinated pesticides.

An additional PRP-led removal action was conducted at the Site in 2005 to remove remaining impacted soils above the 2001 ASAOC performance standards. During the additional excavation work, approximately 14,500 tons of soils and 1,150 tons of concrete were excavated and disposed of off-site at the Waste Management Subtitle D landfill in Tunica Mississippi in accordance with the CERCLA Off-Site Rule. Approximately 7,500 tons of hazardous soil and 32 tons of hazardous concrete were excavated and treated off-site. The hazardous soil was split with roughly 5,500 tons being sent to the Emelle, Alabama facility for stabilization and the remaining tonnage of hazardous soils sent to the Onyx facility in Port Arthur, Texas for incineration. Additionally, 233,000 pounds of tank sludges from eight aboveground storage tanks (ASTs) were also removed and disposed off-site at the Emelle, Alabama facility. Post-excavation sampling confirmed that the 2001 ASAOC performance standards were met. Site excavations conducted in 2001, 2002, and 2005 and sampling of the 18th Street Neighborhood were summarized in the Phase II Soil Removal Report, dated October 2005. It was prepared by site PRP's and approved by the EPA in January 2006.

During the 2005 removal action, the EPA collected 31 composite samples from 30 residential yards in the 18th Street Neighborhood and four groundwater samples from active municipal water supply wells. Two of the municipal wells sampled were approximately 600 feet deep, and the other two municipal wells were approximately 1,000 feet deep. All samples were analyzed for pesticides, aluminum, arsenic, and iron. Of the 30 residences sampled, 26 samples were above background concentrations for pesticides, with dieldrin exceeding the performance standard in 11 samples and toxaphene exceeding the performance standard in four samples. Sample detections were located near the foundations of the residences and the exceedances were determined to be the result of the application of dieldrin-based termiticide, therefore further removal was not conducted at the residences as the elevated results were not considered site related. No pesticides were detected in the groundwater samples and metals were not detected at elevated concentrations in any samples. Residential sampling conducted in the 18th St. Neighborhood and groundwater samples collected from municipal water supply wells were summarized in a Removal Assessment Letter Report, dated December 2005.

In 2007, groundwater samples were collected from nine temporary monitoring wells, one onsite permanent monitoring well, and four municipal water supply wells as part of a Site Inspection. The temporary well samples were collected from between 25 and 45 feet from the top of the casing elevation, depending on depth to water. The permanent monitoring well depth was approximately 48 feet. Eight of the temporary monitoring wells were installed around the perimeter of the Site, with the ninth well being installed in the center of the Site. All well samples were analyzed for volatile organic compounds, semi-volatile organic compounds, metals (including mercury), cyanide, and pesticides; the municipal well samples were also analyzed for polychlorinated biphenyls. The groundwater at the Site had one detection of DDT at a concentration greater than the background well at temporary well TW–07. It should be noted that the groundwater sample collected from TW–07 was collected from perched water exhibiting highly elevated turbidity, and it is believed that the detection was associated with the particulate matter.

In 2010, the EPA conducted a Removal Site Evaluation (RSE) and an air deposition study. A total of 76 locations were sampled in all directions, up to a quarter mile from the Site, including the 18th Street Neighborhood. Composite soil samples were collected from 0 to 3-inches below ground surface (BGS). Pesticides were detected in all the composite samples collected. A total of 32 of the 84 samples (73 composites, 3 background composites, and 8 duplicates) exceeded three times the background concentrations. Sample results from all but one of the locations reflected concentrations below 10^{-5} excess cancer risk levels applicable to the detected COCs. There were four residential properties with dieldrin soil levels detected above the background level of 52 micrograms per kilogram (µg/kg), but below the level of 340 ug/kg which corresponds to 10^{-5} cancer risk for a residential scenario. The four residential property soil detections likely resulted from application of dieldrin-based termiticide as was determined during the 2005 removal action sampling. The air deposition study addressed the potential migration pathway from wind borne dust resulting from normal operations and/or dust from the November 1985 fire at a warehouse at the RPF. At the time, the RPF was no longer a production facility but was a warehousing operation. Statistical analysis comparing pesticide concentrations collected during the EPA's 2010 air deposition study to spatial distance from the RPF showed that concentrations seen in the 18th Street Neighborhood are unlikely to be the result of such air deposition.

A Hazardous Ranking System documentation package was prepared for the Site. The HRS process evaluates the migration and exposure pathways of contaminated site media and gives a numerical score based on the cumulative threat for exposure. For the RPF site, groundwater migration and soil exposure pathways were evaluated. The HRS process yielded a score of 39.43, with 28.5 being the threshold criteria to list a site on the NPL. The Site was proposed to the NPL on 3/10/2011 (76 FR 13113) and placed as final on the NPL on 9/16/2011 (76 FR 57662). The Site CERCLIS ID is MSD000272385.

Remedial Investigation

On September 26, 2016, the EPA entered into another ASAOC with the Red Panther PRPs to perform a Focused Remedial Investigation/Feasibility Study (FRI/FS). The primary purpose of this ASAOC was to determine the nature and extent of contamination and identify any threat to the public health, welfare, or environment caused by the release or threatened release of hazardous substances, pollutants or

contaminants at or from the Site by performing a FRI.

The FRI assessed potential risks posed to residents from dermal contact or accidental ingestion of soils in residential areas or off-site drainage areas; to industrial or commercial workers from dermal contact or accidental ingestion of soils at the RPF or IP; to accidental ingestion of groundwater from the Mississippi aquifer; and to ecological receptors.

The 2018 FRI included sediment sampling, soil sampling, installation of three groundwater monitoring wells, and groundwater sampling within four main areas. Those four areas included: The RPF, a vacant IP located immediately south-southeast of the RPF, a storm sewer drainage ditch located approximately 0.5 miles southwest of the RPF, and five residential properties located west of the RPF.

A significant component of the HRS score, which led to placement of the Site on the NPL, was the elevated concentration of pesticides detected in a single monitoring well. One of the primary objectives of the FRI was to determine the nature and extent of any groundwater contamination. The FRI sampling results indicate that soil, sediment, and groundwater at the Site do not pose any unacceptable human health risks to current and future receptors that exceed the acceptable EPA risk range of 10^{-4} to 10^{-6} cancer risk. Groundwater results were less than three times the background well concentration and confirmation results for dieldrin were five times lower than the tapwater regional screening level (RSL). Soils evaluated at the RPF indicated pesticide concentrations less than the industrial risk level established by the site-specific risk assessment. Soil samples collected at 18th Street Neighborhood residential properties were all below the associated RSLs, except for samples collected near the foundations. The exceedances in the foundation samples was determined to be related to termiticide usage. Inclusion of aliquots from those foundations biased prior results obtained during prior sampling events, including the soil exposure pathway used for HRS scoring. Additionally, the groundwater sampling conducted during the FRI ruled out groundwater contamination as a human health risk, thus the EPA selected a no-further-action remedy and is proposing to delete the Site from the NPL.

In addition, the May 2020 Review of Removal Action Confirmatory Data Memorandum (Memorandum) from the Site Human Health Risk Assessor (HHRA) evaluated the data from four IP samples that would be considered surface soil for purposes of residential human exposure (no deeper than 1 foot). The data from these samples were analyzed for arsenic, dieldrin, and toxaphene. The HHRA compared the confirmatory sample data to health risk-based levels for a chronic, daily residential receptor scenario and found none of the samples had reported levels of these analytes that would pose a summed excess cancer risk exceeding 10^{-4}, or a noncancer hazard quotient (HQ) exceeding 1. The Memorandum further stated that the same conclusion is reached even if the maximum level for each contaminant from the four sample locations is assumed for chronic residential exposure. Based upon these reported surface soil data, the Site is protective of human health and the environment and does not require use restrictions.

Cancer risk estimates from the HHRA indicate no unacceptable cancer risk is present at the IP from the potentially complete exposure pathways to the potential receptor populations. Similarly, hazard index estimates also indicate no unacceptable non-cancer hazards from the potentially complete exposure pathways to the potential receptor populations.

Removal actions conducted in 2002 and 2005 on the RPF parcels and storm water drainage ditch met established performance standards and left no hazardous substances, pollutants, or contaminants remaining on Site above levels that exceed the threshold for unlimited use and unrestricted exposure (UU/UE). Residential yards, in the 18th St. Neighborhood, sampled during the 2005 removal action and 2010 RSE showed no site-related hazardous substances, pollutants, or contaminants existed above levels for UU/UE. Subsequent sampling and data analysis presented in the 2018 FRI and May 2020 HHRA Memorandum support this conclusion.

Selected Remedy

Based upon FRI sampling results indicating that soil, sediment, and groundwater at the Site do not pose any unacceptable human health risks to current and future receptors, the EPA issued the ROD on August 21, 2019 that selected a remedy of No Further Action. The FRI confirmed that previous removal actions conducted between 2002 through 2005 addressed unacceptable risks to human health and the environment. The Administrative Record for the Red Panther Chemical Company Site is available for review at the Carnegie Public Library, located at 114 Delta Avenue, Clarksdale, Mississippi, and at the EPA Region 4 Records Center in Atlanta, Georgia. The State of Mississippi, as represented by the MDEQ, supported the No Further Action remedial alternative for the Site as protective of human health and the environment.

Institutional Controls

Per the ROD, institutional controls (ICs) are not required to restrict land or groundwater use throughout the Site. As a result of removal actions conducted at the Site between 2002 through 2005, the cleanup achieved the UU/UE threshold and does not require ICs for long-term remedy protectiveness. The RPF currently has an industrial zoning designation and is expected to remain industrial in the future. In addition to the industrial zoning, maximum surface soil concentrations for both dieldrin and toxaphene from the IP assessed in the HHRA showed acceptable risks (*i.e.,* not exceeding 10^{-4} excess cancer risk or HQ of 1) for both industrial and residential receptors.

Community Involvement

The EPA has been actively engaged with the affected community and has strived to maintain a collaborative relationship with those interested residents during the FRI and the remedy selection process.

Determination That the Criteria for Deletion Have Been Met

The EPA has followed all procedures required by 40 CFR 300.425(e), Deletion from the NPL. The EPA consulted with the State of Mississippi prior to developing this Notice. The EPA determined that both the EPA and MDEQ have conducted all appropriate response actions required and that no further response action for the Site is appropriate. The EPA is publishing a notice in a major local newspaper, The Clarksdale Press Register Newspaper, to inform the public of its intent to delete the Site and how to submit comments. The EPA placed copies of documents supporting the proposed deletion in the site information repository; these documents are available for public inspection and copying.

The selected remedial action objectives and associated cleanup levels for the surface and subsurface soils are consistent with agency policy and guidance. Based on information currently available to the EPA, no further Superfund response at the Site is needed to protect human health and the environment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1251 *et seq.*.

Dated: June 26, 2020.

Mary Walker,

Regional Administrator Region 4.

[FR Doc. 2020–14430 Filed 7–14–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[RTID 0648–XY104]

Fisheries of the Exclusive Economic Zone Off Alaska; St. Matthew Blue King Crab Rebuilding Plan in the Bering Sea and Aleutian Islands

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

ACTION: Availability of proposed amendment; request for comments.

SUMMARY: The North Pacific Fishery Management Council submitted Amendment 50 to the Fishery Management Plan (FMP) for Bering Sea/Aleutian Islands (BSAI) King and Tanner Crabs (Crab FMP) (Amendment 50), to the Secretary of Commerce for review. If approved, Amendment 50 would add a new rebuilding plan for St. Matthew blue king crab (SMBKC) to the Crab FMP. The objective of this amendment is to rebuild the SMBKC stock. In order to comply with provisions of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), this action is necessary to implement a rebuilding plan prior to the start of the 2020/2021 fishing season. Amendment 50 is intended to promote the goals and objectives of the Magnuson-Stevens Act, the Crab FMP, and other applicable laws.

DATES: Comments on Amendment 50 must be received no later than September 14, 2020.

ADDRESSES: You may submit comments on this document, identified by NOAA-NMFS–2020–0080, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0080,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of proposed Amendment 50 and the draft Environmental Assessment (referred to as the ''Analysis'') prepared for this action may be obtained from *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Megan Mackey, 907–586–7228.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Act requires that each regional fishery management council submit any FMP amendment it prepares to NMFS for review and approval, disapproval, or partial approval by the Secretary of Commerce (Secretary). The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP amendment, immediately publish notification in the **Federal Register** announcing that the amendment is available for public review and comment. The North Pacific Fishery Management Council (Council) has submitted Amendment 50 to the Secretary for review. This document announces that proposed Amendment 50 is available for public review and comment.

NMFS manages the crab fisheries in the exclusive economic zone under the Crab FMP. The Council prepared the Crab FMP under the authority of the Magnuson-Stevens Act, 16 U.S.C. 1801 *et seq.* Regulations governing U.S. fisheries and implementing the FMP appear at 50 CFR parts 600 and 680.

Through the Crab FMP, the State of Alaska (the State) is delegated management authority over certain aspects of the SMBKC fishery consistent with the Magnuson-Stevens Act and the FMP. Specific to this Crab FMP amendment, the State has established a harvest strategy to set total allowable catch (TAC) levels and guideline harvest levels (GHLs), and season or area closures when the TAC or GHL is reached. The State's SMBKC harvest strategy is provided in the Alaska Administrative Code at 5 AAC 34.917 and that strategy applies during rebuilding. The State harvest strategy is more conservative than the Crab FMP's control rule parameters for SMBKC because, under the State harvest strategy, directed fishing is prohibited at or below a larger biomass level than under the overfishing level (F_{OFL}) control rule.

The SMBKC stock was declared overfished on October 22, 2018, because the estimated spawning biomass was below the minimum stock size threshold specified in the Crab FMP. In order to comply with provisions of the Magnuson-Stevens Act, a rebuilding plan must be implemented prior to the start of the 2020/2021 fishing season.

In June 2020, the Council chose a rebuilding plan for SMBKC that would only allow directed harvest during rebuilding if estimates of stock biomass are sufficient to open the fishery under the State's crab harvest strategy. The proposed rebuilding plan is consistent with the Magnuson-Stevens Act (16 U.S.C. 1854(e)), with the National Standards (see Analysis Section 4.1), and with National Standard Guidelines (50 CFR 600.310) on time for rebuilding, specifically rebuilding within a time (T_{target}) that is as short as possible, taking into account the status and biology of any overfished stocks of fish, the needs of fishing communities, recommendations by international organizations in which the United States participates, and the interaction of the overfished stock of fish with the marine ecosystems. This rebuilding plan would allow directed fishing pursuant to the State's harvest strategy because such fishing, though limited, may provide important economic opportunities for harvesters, processors, and Alaska communities. Maintaining this economic opportunity for a limited directed commercial fishery under the State harvest strategy is important for harvesters, processors, and communities, particularly during this time when the majority of commercial crab stocks are in a state of decline and future openings are likely to be limited and/or closed. Fishermen and

communities must be able to diversify their portfolios and be flexible enough to take advantage of fishing opportunities as they come each season to remain viable.

Under the Magnuson-Stevens Act, the time period specified for rebuilding a fishery generally should not exceed 10 years unless the biology of the stock or environmental conditions dictate otherwise, as is the case for SMBKC. Because ecological conditions represent the primary constraint on rebuilding the SMBKC fishery, the projected time for rebuilding, taking into account the biology of the species and current environmental conditions, is 25.5 years.

The directed fishery has been closed since 2016 under the State harvest strategy, and has only been open 6 out of the past 20 years. In addition to the State's conservative SMBKC harvest policy, multiple measures for habitat protection and bycatch reduction are in place for the stock. The St. Matthew Island Habitat Conservation Area (SMIHCA) was created in 2008 and expanded through Amendment 94 to the BSAI Groundfish FMP to protect blue king crab habitat. Vessels fishing with non-pelagic trawl gear are prohibited from fishing in the SMIHCA. Other fishery closure areas include a 20 nautical miles (nm) closure around the southern tip of Hall Island to trawling, hook-and-line, and pot fisheries for pollock, Pacific cod, and Atka mackerel to protect Steller sea lions, but it also serves to limit potential fishing effort in areas occupied by SMBKC. In addition, State jurisdictional waters (0 to 3 nm from shore) surrounding St. Matthew, Hall, and Pinnacle Islands are closed to the taking of king and Tanner crab and to commercial groundfish fishing.

Fishing mortality is not considered to be the primary constraining factor for SMBKC. The groundfish fisheries incur low levels of bycatch of SMBKC, but in analytical projections, average bycatch rates had no constraining effect on rebuilding. Instead, rebuilding will depend on successful recruitment of crab under ecosystem conditions that have recently been very unfavorable. Warm bottom temperatures, low pre-recruit biomass, and northward movement of predator species, primarily Pacific cod, have constrained stock growth (see Analysis Section 3.3.6). For this reason, the rebuilding plan aims to maintain existing low levels of fishing mortality with the hope that future ecosystem conditions will support SMBKC stock growth.

Amendment 50 would add Section 6.2.5 to the Crab FMP to include the proposed rebuilding plan for SMBKC. Under the proposed rebuilding plan, ecosystem indicators developed for the stock would be monitored in the coming years. The NMFS eastern Bering Sea bottom-trawl survey provides data for the annual assessment of the status of crab stocks in the BSAI, including SMBKC, and this survey and assessment would continue throughout rebuilding. The Council's BSAI Crab Plan Team would report stock status and progress towards the rebuilt level in the Stock Assessment and Fishery Evaluation (SAFE) Report for the king and Tanner crab fisheries of the BSAI. Additionally, the State and NMFS monitor directed fishery catch and bycatch of blue king crabs in other fisheries. When the fishery is open, the State requires full observer coverage (100 percent) for both catcher vessels and catcher processors participating in the crab fishery. Observers monitor harvest at sea and landings by catcher vessels shoreside processors. The State reports the total harvest from the commercial crab fishery and that report will be included annually in the SAFE. The contribution of the rebuilding plan to stock recovery would be additive to measures already in place that limit the effects of fishing activity on SMBKC.

NMFS is soliciting public comments on proposed Amendment 50 through the end of the comment period (see **DATES**). All relevant written comments received by the end of the applicable comment period will be considered by NMFS in the approval/partial approval/disapproval decision for Amendment 50 and addressed in the response to comments in the final decision. Comments received after the end of the applicable comment period will not be considered in the approval/disapproval decision on Amendment 50. To be considered, comments must be received, not just postmarked or otherwise transmitted, by the last day of the comment period (see **DATES**).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 10, 2020.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2020–15318 Filed 7–14–20; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 85, No. 136
Wednesday, July 15, 2020

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc No. AMS–FGIS–20–0038]

Opportunity for Designation in the Fargo, North Dakota, Area; Request for Comments on the Official Agency Servicing This Area

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The designation of the official agency listed below will end on December 31, 2020. We are asking persons or governmental agencies interested in providing official services in the area presently served by this agency to submit an application for designation. In addition, we are asking for comments on the quality of services provided by the following designated agency: North Dakota Grain Inspection Service, Inc. (NDGI).

DATES: Applications and comments must be received by August 14, 2020.

ADDRESSES: Submit applications and comments concerning this notice using the following methods:

- *To apply for Designation:* Use FGISonline (*https://fgisonline.ams.usda.gov*) and then click on the Delegations/Designations and Export Registrations (DDR) link. You will need to obtain an FGISonline customer number and USDA eAuthentication username and password prior to applying.
- *To submit Comments:* Go to *Regulations.gov* (*http://www.regulations.gov*). Instructions for submitting and reading comments are detailed on the site. Interested persons are invited to submit written comments concerning this notice. All comments must be submitted through the Federal e-rulemaking portal at *http://www.regulations.gov* and should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

Read Applications and Comments: All comments will be available for public inspection online at *http://www.regulations.gov.* If you would like to view the applications, please contact us at *FGISQACD@usda.gov* (7 CFR 1.27(c)).

FOR FURTHER INFORMATION CONTACT: Robert Waller, 816–866–2224 or *FGISQACD@usda.gov.*

SUPPLEMENTARY INFORMATION: Section 7(f) of the United States Grain Standards Act (USGSA) authorizes the Secretary to designate a qualified applicant to provide official services in a specified area, after determining that the applicant is better able than any other applicant to provide such official services (7 U.S.C. 79(f)). Under section 7(g) of the USGSA (7 U.S.C. 79(g)), designations of official agencies are effective for no longer than five years, unless terminated by the Secretary, and may be renewed according to the criteria and procedures prescribed in section 7(f) of the USGSA.

Area Open for Designation

Pursuant to Section 7(f)(2) of the USGSA, the following geographic area, in the states of Illinois, Indiana, Michigan, Minnesota, North Dakota, and Ohio, is assigned to NDGI:

In Illinois

Bounded on the east by the eastern Cumberland County line; the eastern Jasper County line south to State Route 33; State Route 33 east-southeast to the Indiana-Illinois State line; the Indiana-Illinois State line south to the southern Gallatin County line; bounded on the south by the southern Gallatin, Saline, and Williamson County lines; the southern Jackson County line west to U.S. Route 51; U.S. Route 51 north to State Route 13; State Route 13 northwest to State Route 149; State Route 149 west to State Route 3; State Route 3 northwest to State Route 51; State Route 51 south to the Mississippi River; and bounded on the west by the Mississippi River north to the northern Calhoun County line; bounded on the north by the northern and eastern Calhoun County lines; the northern and eastern Jersey County lines; the northern Madison County line; the western Montgomery County line north to a point on this line that intersects with a straight line, from the junction of State Route 111 and the northern Macoupin County line to the junction of Interstate 55 and State Route 16 (in Montgomery County); from this point southeast along the straight line to the junction of Interstate 55 and State Route 16; State Route 16 east-northeast to a point approximately one mile northeast of Irving; a straight line from this point to the northern Fayette County line; the northern Fayette, Effingham, and Cumberland County lines.

In Indiana

Bartholomew, Blackford, Boone, Brown, Carroll (south of State Route 25), Cass, Clinton, Delaware, Fayette, Fulton (bounded on east by eastern Fulton County line south to State Route 19; State Route 19 south to State Route 114; State Route 114 southeast to the eastern Fulton County line), Grant, Hamilton, Hancock, Hendricks, Henry, Howard, Jay, Johnson, Madison, Marion, Miami, Monroe, Montgomery, Morgan, Randolph, Richmond, Rush (north of State Route 244), Shelby, Tipton, Union, and Wayne Counties.

In Michigan

Bounded on the west by State Route 127 at the Michigan-Ohio State line north to State Route 50; bounded on the north by State Route 50 at State Route 127 east to the Michigan State line; the Michigan State line south to the Michigan-Ohio State line.

In Minnesota

Koochiching, St. Louis, Lake, Cook, Itasca, Norman, Mahnomen, Hubbard, Cass, Clay, Becker, Wadena, Crow Wing, Aitkin, Carlton, Wilkin, and Otter Tail Counties, except those export port locations within the state, which are serviced by the Wisconsin Department of Agriculture, Trade and Consumer Protection.

In North Dakota

Bounded on the north by the northern Steele County line from State Route 32 east; the northern Steele and Trail County lines east to the North Dakota State line; bounded on the east by the

eastern North Dakota State line; bounded on the south by the southern North Dakota State line west to State Route 1; and bounded on the west by State Route 1 north to Interstate 94; Interstate 94 west to State Route 1; State Route 1 north to State Route 200; State Route 200 east to State Route 45; State Route 45 north to State Route 32; State Route 32 north.

In Ohio

The northern Ohio State line east to the to the Ohio-Pennsylvania State line; bounded on the east by the Ohio-Pennsylvania State line south to the Ohio River; bounded on the south by the Ohio River south-southwest to the western Scioto County line; and bounded on the west by the western Scioto County line north to State Route 73; State Route 73 northwest to U.S. Route 22; U.S. Route 22 west to U.S. Route 68; U.S. Route 68 north to Clark County; the northern Clark County line west to Valley Pike Road; Valley Pike Road north to State Route 560; State Route 560 north to U.S. Route 36; U.S. Route 36 west to the eastern Miami County line; the eastern Miami County line to the northern Miami County line; the northern Miami County line west to Interstate 75; Interstate 75 north to State Route 47; State Route 47 northeast to U.S. Route 68 (including all of Sidney, Ohio); U.S. Route 68 north to the southern Hancock County line; the southern Hancock County line west to the western Hancock, Wood, and Lucas County lines north to the Michigan-Ohio State line; the Michigan-Ohio State line west to State Route 127; plus all of Darke County.

NDGI's assigned geographic area does not include the export port locations inside the state of Ohio, which are serviced by the Federal Grain Inspection Service.

The following grain elevators are not part of this geographic area assignment and are assigned to Titus Grain Inspection, Inc.: The Andersons, Delphi, Carroll County; Frick Services, Inc., Leiters Ford, Fulton County; and Cargill, Inc., Linden, Montgomery County, Indiana.

Opportunity for Designation

Interested persons or governmental agencies may apply for designation to provide official services in the geographic area specified above under the provisions of section 7(f) of the USGSA and 7 CFR 800.196. Designation in the specified geographic area in Illinois, Indiana, Michigan, Minnesota, North Dakota, and Ohio is for the period beginning January 1, 2021, to December 31, 2025. To apply for designation, please apply at FGISonline (*https://fgisonline.ams.usda.gov*); or, to request more information, contact Robert Waller at the email address or telephone number listed above.

Request for Comments

In this designation process, we are requesting comments on the quality of services provided by the NDGI official agency. We are, also, interested in receiving comments citing reasons and pertinent data supporting or objecting to the designation of an applicant. Such comments should be submitted through the Federal e-rulemaking portal at *http://www.regulations.gov.*

We consider applications, comments, and other available information when determining which applicants will be designated.

Authority: 7 U.S.C. 71–87k.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–15200 Filed 7–14–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0059]

Notice of Request for Extension of Approval of an Information Collection; Johne's Disease in Domestic Animals

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with its efforts to control Johne's disease in the United States.

DATES: We will consider all comments that we receive on or before September 14, 2020.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0059.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0059, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0059* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on Johne's disease, contact Dr. Brianna Schur, Assistant Director, Cattle Health Center VS, APHIS, 920 Main Campus Dr., Suite 200, Raleigh, NC 27606; (919) 855–7240, or at *Brianna.W.Schur@usda.gov.* For more information about the information collection process, contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Johne's Disease in Domestic Animals.

OMB Control Number: 0579–0338.

Type of Request: Extension of approval of an information collection.

Abstract: Under the authority of the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture is authorized, among other things, to prohibit or restrict the importation and interstate movement of animals and animal products to prevent the introduction into and dissemination within the United States of livestock diseases and pests.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing APHIS' ability to compete in the world market of animal and animal product trade. Johne's disease affects cattle, sheep, goats, and other ruminants. It is an incurable and contagious disease that results in progressive wasting and eventual death. The disease is nearly always introduced into a healthy herd by an infected animal that is not showing symptoms of the disease.

The regulations in 9 CFR part 80 pertain specifically to the interstate movement of domestic animals that are positive to an official test for Johne's disease. These regulations provide that cattle, sheep, goats, and other domestic animals that are positive to an official test for Johne's disease may generally be moved interstate only to a recognized slaughtering establishment or to an approved livestock facility for sale to

such an establishment. However, they may also be moved for purposes other than slaughter under certain conditions. Moving Johne's-positive livestock interstate for slaughter or for other purposes without increasing the risk of disease spread requires a movement permit or an owner-shipper statement, official ear tags, and a permission to move request. Permission may also be sought, in writing, for movement of animals that do not have a permit, owner-shipper statement, or ear tags.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.69 hours per response.

Respondents: Accredited veterinarians, herd owners, and livestock shippers.

Estimated annual number of respondents: 7.

Estimated annual number of responses per respondent: 2.

Estimated annual number of responses: 13.

Estimated total annual burden on respondents: 9 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 10th day of July 2020.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–15249 Filed 7–14–20; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Best Practices in Disaster Supplemental Nutrition Assistance Program (D–SNAP) Operations and Planning

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection for the Best Practices in Disaster SNAP Operations and Planning study. This is a new information collection request. This study informs the U.S. Department of Agriculture's (USDA) Food and Nutrition Service (FNS) about best practices in planning for and implementing D–SNAP.

DATES: Written comments must be received on or before September 14, 2020.

ADDRESSES: Comments may be sent to Eric Williams, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, Alexandria, VA 22314. Comments may also be submitted via email at *eric.williams@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of FNS during regular business hours (8:30 a.m. to 5:00 p.m. Monday through Friday) at 1320 Braddock Place, Alexandria, VA 22314.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Eric Williams at (703) 305–2640.

SUPPLEMENTARY INFORMATION: Comments are invited 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, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Best Practices in Disaster Supplemental Nutrition Assistance Program (D–SNAP) Operations and Planning.

Form Number: Not Applicable.

OMB Number: 0584–NEW.

Expiration Date: Not Yet Determined.

Type of Request: New Information Collection Request.

Abstract: Section 17 [7 U.S.C. 2026] (a)(1) of the Food and Nutrition Act of 2008, as amended, provides general legislative authority for the planned data collection. It authorizes the Secretary of Agriculture to enter into contracts with private institutions to undertake research that will help to improve the administration and effectiveness of the Supplemental Nutrition Assistance Program (SNAP).

FNS is conducting this study to identify and document best practices in D–SNAP planning and operations from across the country and for a variety of disaster types. The project will give FNS a better understanding of what works when States implement D–SNAP to provide better direction to States when developing plans and implementing the program. FNS has identified five objectives for this study:

1. Assess the implementation and operation of D–SNAP for selected disaster(s) in each study State.

2. Describe the characteristics and economic circumstances of the D–SNAP households for the selected disaster(s).

3. Document each State's approach to protecting program integrity while operating D–SNAP for the selected disaster(s).

4. Determine best practices for developing annual disaster plans to address a variety of disaster types.

5. Determine best practices for implementing and operating D–SNAP for a variety of disaster types.

The study will gather data through extant administrative SNAP caseload data (already approved under OMB

Control Number: 0584–0064; Expiration Date: 07/31/2020; and under OMB Control Number: 0584–0037; Expiration Date: 02/28/2021), document review, and site visits to five States. The study will focus on 10 recent county or local government administered D–SNAPs across the 5 study States. Each site visit will include interviews with staff at (1) the State SNAP agency, (2) the county SNAP office (if SNAP is county-administered), (3) one local SNAP office near the D–SNAP site, and (4) relevant stakeholders that supported the D–SNAP (*e.g.,* community-based organizations, SNAP retailers). The study team will also seek to interview any former State staff who were closely involved with D–SNAP planning and operations for the relevant disasters. These data will provide information on D–SNAP planning, operations, challenges, best practices, and lessons learned. SNAP administrative caseload data about SNAP participants will be used to examine the characteristics and economic circumstances of D–SNAP households and estimate the economic impact in the affected areas. In some cases, State SNAP offices staff may be asked to provide documentation related to the D–SNAP(s), such as promotional or training materials. These documents will inform the site visits and provide further information on D–SNAP planning and operations. The data collected will be kept private. It will not be shared with anyone outside the study team and FNS research and administrative staff.

Affected Public: (1) State, Local and Tribal Governments; (2) Business (For Profit and Not for Profit); and (3) Individuals/Households.

Respondent groups identified include the following:

1. *State, Local, and Tribal Government:* State SNAP directors, State D–SNAP policy leads, State emergency response managers in 5 study States; State information technology, civil rights, and communications staff in 5 study States; State database administrators in 5 study States; County SNAP directors, County D–SNAP policy leads, and County emergency response managers in 4 study counties across 2 study States; Local SNAP office staff in each of the 5 study States; we anticipate 100 percent participation from this affected public.

2. *Business (For Profit and Not For Profit):* Staff at stakeholder organizations, SNAP retailers such as grocery stores or community-based organizations.

3. *Individuals:* Former State or local staff who no longer work for the government.

Estimated Number of Respondents: The total estimated number of respondents is 233 (122 State, Local, and Tribal Government staff, 55 Business (For Profit and Not For Profit) staff, and 56 Individuals). Of the 233 contacted, 224 are estimated to be responsive and 9 are estimated to be nonresponsive. The breakout of respondents follows:

1. *126 State, Local, and Tribal Government staff:* Of the 35 State SNAP staff contacted, 35 are estimated to be responsive; of the 16 County SNAP staff contacted, 16 are estimated to be responsive; of the 15 State database administrators contacted, 15 are estimated to be responsive; of the 70 Local office staff contacted, 70 are estimated to be responsive.

2. *55 Business (For Profit and Not For Profit) staff:* Of the 55 Business stakeholder staff contacted, 50 are estimated to be responsive; and 5 will be non-responsive.

3. *56 Individuals:* Of the 56 individuals contacted, 52 are estimated to be responsive and 4 will be non-responsive.

Estimated Number of Responses per Respondent: 1.00—based on 247 total annual responses (238 responsive and 9 nonresponsive) made by the 233 respondents (238 responsive and 9 nonresponsive). See table 1 for the estimated number of responses per respondent for each type of respondent.

The estimate breakout follows:

1. *State SNAP Staff (30):* The estimated number of responses per State SNAP staff is 1.00:

- 5 State SNAP directors will respond to advance materials and scheduling, including submission of D–SNAP documentation; the same 5 State SNAP directors plus 5 additional D–SNAP policy leads and 5 additional emergency response managers will take part in an in-person interview during the site visit. 5 State information technology staff, 5 State communications staff, and 5 State civil rights staff will take part in an in-person interview during the site visit.

2. *County SNAP Staff (12):* The estimated number of responses per County SNAP staff is 1.00:

- 4 County SNAP directors will respond to advance materials and scheduling, including submission of D–SNAP documentation; the same 4 County SNAP directors plus 4 additional D–SNAP policy leads and 4 additional emergency response managers will take part in an in-person interview during the site visit.

3. *State SNAP Database Administrators (10):* The estimated number of responses per State SNAP database administrator is 1.00:

- 5 State SNAP database administrators will respond to advance materials and scheduling; 5 State SNAP database junior staffers will submit a test datafile and the same 5 State SNAP database junior staffers will submit a final administrative datafile.

4. *Local SNAP Office Staff (70):* The estimated number of responses per Local SNAP office staff is 1.00:

- 10 Local SNAP office directors will respond to advance materials and scheduling, including submission of D–SNAP documentation; the same 10 Local SNAP office directors will take part in an in-person interview; 50 additional Local SNAP office staff will take part in a group discussion during the site visit; and an additional 10 Local SNAP office staff will take part in observations of the D–SNAP and disaster sites during the site visit.

5. *Business (For Profit and Not for Profit) D–SNAP Stakeholder Staff (55):* The estimated number of responses per Business stakeholder staff is 1.00:

- Of 30 Business D–SNAP stakeholder staff, 25 will respond to advance materials and scheduling, including submission of D–SNAP documentation (5 will not respond to advance materials and scheduling); 25 staff will take part in an in-person interview during the site visit, we anticipate these will be different responders.

6. *Individuals (Former State/Local Government Officials no Longer Working in Government) (30):* The estimated number of responses per Individual is 1.00:

- Of 10 Individuals who previously worked for the State government, 8 will respond to advance materials and scheduling (2 will not respond to the advance materials and scheduling); the 8 individuals who responded to the advance materials will take part in an interview.

- Of 20 Individuals who previously worked for the County/Local government, 18 will respond to advance materials and scheduling (2 will not respond to the advance materials and scheduling); the 18 individuals who responded to the advance materials will take part in an interview.

Estimated Total Frequency Response per Respondent: 1.0600858369. FNS anticipate on response per respondent although some State, Local or Tribal staff may participate in more than one (1) activity.

Estimated Total Annual Responses: 247 (238 annual responses for responsive participants and 9 annual responses for nonresponsive participants).

Estimated Time per Response: 1.90870445 hours (2.07 hours for responsive participants and 0.05 hours for nonresponsive participants). The estimated time of response varies from 0.05 hours to 10 hours depending on respondent group and activity, as shown in table 1.

Estimated Total Annual Burden on Respondents and Non-Respondents: 471.45 hours (471 hours for responsive participants, and 0.45 hours for nonresponsive participants). See table 1 for estimated total annual burden for each type of respondent.

TABLE 1—TOTAL PUBLIC BURDEN HOURS

Respondent category	Type of respondent	Instruments and activities	Sample size	Responsive					Nonresponsive					Grand total annual burden estimate (hours)
				Number of respondents	Frequency of response	Total annual responses	Hours per response	Annual burden (hours)	Number of non-respondents	Frequency of response	Total annual responses	Hours per response	Annual burden (hours)	
State, Local, and Tribal Government														
State/local/tribal government subtotal.	State SNAP Directors* (1 per State).	Advance materials and preparation, including all conference and scheduling calls, and submission of documents.	5	5	1	5	4	20	0	0	0	0	0	20
	State SNAP Directors* (1 per State); D–SNAP Policy Lead (1 per State), and Emergency Response Manager (1 per State).	In-person semi-structured interviews in 5 States.	15	15	1	15	3	45	0	0	0	0	0	45
	State information technology staff (1 per State), civil rights staff (1 per State), and communications staff (1 per State).	In-person semi-structured interviews in 5 States.	15	15	1	15	1	15	0	0	0	0	0	15
	Subtotal for State SNAP staff		30	30	1.167	35	2.3	80	0	0	0	0	0	80
	County SNAP Directors*** (2 per State, in 2 States).	Advance materials and preparation, including all conference and scheduling calls, and submission of documents.	4	4	1	4	4	16	0	0	0	0	0	16
	County SNAP Directors (2 per State, in 2 States), D–SNAP policy lead (2 per State, in 2 States), and emergency response managers (2 per State, in 2 States).	In-person semi-structured interviews in 4 counties.	12	12	1	12	3	36	0	0	0	0	0	36
	Subtotal for county SNAP staff		12	12	1	16	3	52	0	0	0	0	0	52
	State SNAP Database administrator (1 per State).	Advance materials and preparation, including consultative data call.	5	5	1	5	3	15	0	0	0	0	0	15
	State SNAP Database junior staffer (1 per State).	Submit test file and submit final file	5	5	2	10	4	40	0	0	0	0	0	40
	Subtotal for State database administrator		10	10	2	15	3.67	55	0	0	0	0	0	55
	Local SNAP Office Director** (2 per State in 5 States).	Advance materials and preparation, including submission of documents.	10	10	1	10	2	20	0	0	0	0	0	20
	Local SNAP Office Director** (the same 2 per State in 5 States that received and reviewed the advance materials).	In-person semi-structured interviews with 1 SNAP director/manager at 10 sites.	10	10	1	10	1	10	0	0	0	0	0	10
	Local SNAP Office staff (on average, 10 per State in 2 States).	Group discussion with 5 local staff at 10 sites.	50	50	1	50	2	100	0	0	0	0	0	100
	Local SNAP Office staff (2 per State in 5 States).	Observations of D–SNAP and disaster site with SNAP director/manager at 10 sites.	10	10	1	10	4	40	0	0	0	0	0	40
	Subtotal for local SNAP office		70	70	1	70	2.43	170	0	0	0	0	0	170
State/local/tribal government subtotal			122	122	1	136	2.63	357	0	0	0	0	0	357
Business														
Business (for profit and not for profit).	D–SNAP stakeholder (3 per disaster).	Advance materials and preparation, including submission of documents.	30	25	1	25	2	50	5	1	5	0.05	0.25	50.25
	D–SNAP stakeholder (3 per disaster).	In-person semi-structured interviews with 1 staff member at 25 stakeholder offices.	25	25	1	25	1	25	0	0	0	0	0	25
Business subtotal			55	50	1	50	2	75	5	1	5	0.05	0.25	75.25

Individuals													
Individuals	Former State office D–SNAP staff (1 per disaster).	Advance letter and other recruitment.	10	8	1	8	0.5	4	2	1	2	0.05	0.1	4.1
	Former State office D–SNAP staff (8 from among those receiving the advance letter).	In-person semi-structured interview	8	8	1	8	1	8	0	0	0	0	0	8
	Former local office D–SNAP staff (2 per disaster).	Advance letter and other recruitment.	20	18	1	18	0.5	9	2	1	2	0.05	0.1	9.1
	Former local office D–SNAP staff (8 from among those receiving the advance letters).	In-person semi-structured interview	18	18	1	18	1	18	0	0	0	0	0	18
Individuals subtotal			56	52	1	52	0.75	39	4	1	4	0.05	0.2	39.2
Total			233	224	1.062500	238	1.98	471	9	1	9	0.05	0.45	471.45

*The unique 5 State SNAP Directors respondents are counted once although they participated in multiple activities.
**The unique 10 Local SNAP Office Directors are counted once although they participated in multiple activities.
***The unique 4 Count SNAP Directors are counted once although they participated in multiple activities.

Pamilyn Miller,

Administrator, Food and Nutrition Service.

[FR Doc. 2020–15218 Filed 7–14–20; 8:45 am]

BILLING CODE 3410–30–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Delaware 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 planning meeting of the Delaware Advisory Committee to the Commission will convene by conference call, on Wednesday, August 5, 2020 at 1:00 p.m. (EDT). The purpose of the meeting is for project planning and selection of additional Committee officers.

DATES: Wednesday, August 5, 2020 at 1:00 p.m. (EDT).

Public Call-In Information: Conference call number: 1–800–367–2403 and conference call ID: 4195799.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call number: 1–800–367–2403 and conference call ID: 4195799. Please be advised that before placing them into the conference call, the conference call operator may ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number herein.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call number:1–800–822–2024 and conference call ID: 4195799.

Members of the public are invited make statements during the Public Comment section of the meeting or to submit written comments; the written comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425 or emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing, as they become available at this *FACA link*, click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. 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 Eastern Regional Office at the above phone number, email or street address.

Agenda

Wednesday, August 5, 2020 at 1:00 p.m. (EDT)

I. Welcome and Roll Call
II. Project Planning
III. Other Business
IV. Next Planning Meeting
V. Public Comments
VI. Next Meeting
VII. Adjourn

Dated: July 10, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–15264 Filed 7–14–20; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the North Carolina Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the North Carolina Advisory Committee (Committee) will hold a series of web based hearings to hear from speakers and discuss legal financial obligations in North Carolina.

DATES: The hearings will take place on:

- (Session II) Thursday July 23, 12:00 p.m.—2:00 p.m. EST
- (Session III) Thursday August 13, 12:00 p.m.—2:00 p.m. EST

Public Call Information: (both sessions) Dial: 800–367–2403; Conference ID: 3730396.

FOR FURTHER INFORMATION CONTACT: Mallory Trachtenberg, DFO, at *mtrachtenberg@usccr.gov* or 202–809–9618.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. These meetings are free and open to the public through the above listed toll-free number. Members of the public may join through the above listed toll-free number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call-in number: 800–367–2403 and conference ID number 3730396.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Mallory Trachtenberg at *mtrachtenberg@usccr.gov* in the Regional Programs Unit Office/Advisory Committee Management Unit. Persons who desire additional information may contact the Regional Program Unit at 202–809–9618.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *https://www.facadatabase.gov/FACA/apex/FACAPublicCommittee?id=a10t0000001gzldAAA* under the Commission on Civil Rights, North Carolina Advisory Committee link. Persons interested in the work of this Committee are also directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit office at the above email or phone number.

Agenda

I. Welcome

II. Announcements and Updates
III. Approval of Minutes From the Last Meeting
IV. Briefing: Civil Rights Project on Legal Financial Obligations
V. Future Plans and Actions
VI. Public Comment
VII. Adjournment

Dated: July 9, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–15225 Filed 7–14–20; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the New Jersey 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 planning meeting of the New Jersey Advisory Committee to the Commission will convene by conference call, on Friday, August 21, 2020 at 1:00 p.m. (EDT). The purpose of the meeting is to receive updates from the Forfeiture and Licensing Workgroups about suggestions for planning the Committee's briefing to examine its civil rights project on the collateral consequences that a criminal record has on criminal asset forfeitures and occupational licensing.

DATES: Friday, August 21, 2020, at 1:00 p.m. (EDT).

Public Call-In Information:

Conference call number: 1–800–667–5617 and conference call ID number: 7386659.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call number: 1–800–667–5617 and conference call ID number: 7386659. Please be advised that before placing them into the conference call, the conference call operator may ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number herein.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call number:1–800–667–5617and conference call ID number: 7386659.

Members of the public are invited to make statements during the Public Comment section of the meeting or to submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, or emailed to Ivy Davis at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing, as they become available at this FACA link, click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. 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 Eastern Regional Office at the above phone number, email or street address.

Agenda

Friday, August 21, 2020 at 1:00 p.m. (EDT)

I. Roll Call
II. Welcome
III. Project Planning
IV. Other Business
V. Next Meeting
VI. Public Comments
VII. Adjourn

Dated: July 10, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–15261 Filed 7–14–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–19–2020]

Foreign-Trade Zone (FTZ) 77—Memphis, Tennessee, Authorization of Production Activity, ISK Biosciences Corporation (Agricultural Chemicals), Memphis, Tennessee

On March 12, 2020, the City of Memphis, grantee of FTZ 77, submitted a notification of proposed production activity to the FTZ Board on behalf of ISK Biosciences Corporation, within Subzone 77I, in Memphis, Tennessee.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (85 FR 17310, March 27, 2020). On July 10, 2020, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: July 10, 2020.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2020–15284 Filed 7–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–059]

Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel From the People's Republic of China: Rescission of Countervailing Duty Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on cold-drawn mechanical tubing of carbon and alloy steel (CDMT) from the People's Republic of China (China) for the period of review (POR) January 1, 2019, through December 31, 2019, based on the timely withdrawal of the request for review.

DATES: Applicable July 15, 2020.

FOR FURTHER INFORMATION CONTACT: Shanah Lee, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401

Constitution Ave NW, Washington DC 20230; telephone: (202) 482–6386.

SUPPLEMENTARY INFORMATION:

Background

On February 3, 2020, Commerce published a notice of opportunity to request an administrative review of the CVD order on CDMT from China for the POR of January 1, 2019, through December 31, 2019.[1] On March 2, 2020, Commerce received a timely-filed request from ArcelorMittal Tubular Products LLC and Webco Industries, Inc. (collectively, the petitioners) for an administrative review of 22 producers and exporters, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[2]

On April 8, 2020, pursuant to this request, and in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice initiating an administrative review of the CVD order on CDMT from China for the 22 producers and exporters.[3] On June 18, 2020, the petitioners withdrew their request for an administrative review of all 22 producers and exporters.[4] On June 23, 2020, Zhejiang Minghe Steel Pipe Co., Ltd. (Minghe), the sole mandatory respondent selected in this review, acknowledged the domestic interested parties' withdrawal request.[5]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. The domestic interested parties withdrew their request for review of all of the 22 producers and exporters for which they had requested an administrative review. No other parties requested an administrative review of the order. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding this review in this entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries of CDMT from China. Countervailing duties shall be assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to all 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. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: July 8, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–15281 Filed 7–14–20; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Antidumping and Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 5938 (February 3, 2020).

[2] *See* Petitioners' Letter, ''Cold-Drawn Mechanical Tubing from the People's Republic of China—Domestic Industry's Request for 2019 Second Administrative Review,'' dated March 2, 2020.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 19730 (April 8, 2020).

[4] *See* Petitioners' Letter, ''Certain Cold-Drawn Mechanical Tubing from the People's Republic of China—Domestic Producers Withdrawal of Request for 2019 Countervailing Duty Administrative Review,'' dated June 18, 2020.

[5] *See* Minghe's Letter, ''Certain Cold-Drawn Mechanical Tubing from China: Rescission of Review; Suspension of Questionnaire Requirements,'' dated June 23, 2020.

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free Trade Agreement (NAFTA), Article 1904 Binational Panel Review: Notice of Completion of Panel Review

AGENCY: United States Section, NAFTA Secretariat, International Trade Administration, Department of Commerce.

ACTION: Notice of completion of panel review of the determination on remand by the United States International Trade Commission in the matter of Softwood Lumber Injury from Canada (Secretariat File Number: USA–CDA–2018–1904–03).

SUMMARY: Pursuant to the Final Panel Decision and Order dated May 22, 2020, in the matter of Softwood Lumber Injury from Canada (Determination on Remand), the Panel Review was completed on July 9, 2020.

FOR FURTHER INFORMATION CONTACT: Paul E. Morris, United States Secretary, NAFTA Secretariat, Room 2061, 1401 Constitution Avenue NW, Washington, DC 20230, (202) 482–5438, *tradeagreementssecretariat@trade.gov.*

SUPPLEMENTARY INFORMATION: Chapter 19 of Article 1904 of NAFTA provides a dispute settlement mechanism involving trade remedy determinations issued by the Government of the United States, the Government of Canada, and the Government of Mexico. Following a Request for Panel Review, a Binational Panel is composed to review the trade remedy determination being challenged and issue a binding Panel Decision. There are established *NAFTA Rules of Procedure for Article 1904 Binational Panel Reviews (Rules)* and in accordance with Rule 80, the Panel Review was completed and the panelists were discharged from their duties effective July 9, 2020. For the complete *Rules,* please see *https://can-mex-usa-sec.org/secretariat/agreement-accord-acuerdo/nafta-alena-tlcan/rules-regles-reglas/index.aspx?lang=eng.*

Dated: July 9, 2020.

Paul E. Morris,

U.S. Secretary, NAFTA Secretariat.

[FR Doc. 2020–15251 Filed 7–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–879, A–588–861]

Polyvinyl Alcohol From the People's Republic of China and Japan: Final Results of the Expedited Sunset Reviews of the Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these sunset reviews, the Department of Commerce (Commerce) finds that revocation of the antidumping duty orders on polyvinyl alcohol (PVA) from the People's Republic of China (China) and Japan would be likely to lead to continuation or recurrence of dumping as indicated in the ''Final Results of Review'' section of this notice.

DATES: Applicable July 15, 2020.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita at (202) 482–4243, AD/

CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2020, Commerce published the *Notice of Initiation* of the sunset reviews of the antidumping duty orders on PVA from China and Japan pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1]

Commerce received notices of intent to participate from Sekisui Specialty Chemical America, LLC (Sekisui Specialty Chemical) and Kuraray America, Inc. (Kuraray) (collectively, domestic interested parties) within the deadline specified in 19 CFR 351.218(d)(1)(i). The companies claimed interested party status under section 771(9)(C) of the Act as producers of a domestic like product in the United States.

Commerce received complete substantive responses to the *Notice of Initiation* from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). We received no substantive responses from any other interested parties with respect to any of the orders covered by these sunset reviews, nor was a hearing requested. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted expedited (120-day) sunset reviews of the antidumping duty orders for China and Japan.

Scope of the Orders

The merchandise covered by these orders is PVA. This product consists of all PVA hydrolyzed in excess of 80 percent, whether or not mixed or diluted with commercial levels of defoamer or boric acid, except as noted below.[2]

The merchandise subject to these orders is currently classifiable under subheading 3905.30.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of these orders is dispositive.

[1] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 18189 (April 1, 2020) (*Notice of Initiation*).

[2] For a full description of the scope of the order, *see* Memorandum, ''Decision Memorandum for the Expedited Sunset Reviews of the Antidumping Duty Orders on Polyvinyl Alcohol from China and Japan,'' dated concurrently with, and hereby adopted by, this notice (Decision Memorandum).

Analysis of Comments Received

All issues raised in these reviews are addressed in the Decision Memorandum, which is hereby adopted by this notice. The issues discussed in the Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margins of dumping likely to prevail if the orders were revoked. The 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://iaaccess.trade.gov.* In addition, a complete version of the Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Decision Memorandum are identical in content.

Final Results of Reviews

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the antidumping duty orders on PVA from China and Japan would be likely to lead to continuation or recurrence of dumping, and that the margins of dumping likely to prevail would be weighted-average margins of up to 97.86 percent for China and 144.16 percent for Japan.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely notification of the destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notifications to Interested Parties

We are issuing and publishing these results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.221(c)(5)(ii).

Dated: July 9, 2020.

Joseph A. Laroski Jr.,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix

[FR Doc. 2020–15282 Filed 7–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA249]

Fisheries of the Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 65 Assessment Webinar VI for Highly Migratory Species Atlantic Blacktip Shark.

SUMMARY: The SEDAR 65 assessment of the Atlantic stock of blacktip shark will consist of a series of workshops and webinars: Data Workshop; Assessment Webinars; and a Review workshop.

DATES: The SEDAR 65 Assessment Webinar VI has been scheduled for July 30, 2020, from 10 a.m. to 1 p.m. EDT

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Registration is available online at: *https://attendee.gotowebinar.com/register/4887094297657430029.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366; email: *Kathleen.Howington@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data

Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the Assessment webinar VI are as follows:

• Review projection results for finalized reference case model run(s) and finalize any changes to the projections.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 9, 2020.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–15217 Filed 7–14–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA245]

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 70 Assessment Webinar II for Gulf of Mexico greater amberjack.

SUMMARY: The SEDAR 70 stock assessment process for Gulf of Mexico greater amberjack will consist of a series of data and assessment webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 70 Assessment Webinar II will be held Thursday, July 30, 2020, from 1 p.m. until 3 p.m. Eastern Time.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the Assessment Webinar are as follows:

1. Using datasets and initial assessment analysis recommended from the data webinars, panelists will employ assessment models to evaluate stock status, estimate population benchmarks and management criteria, and project future conditions.

2. Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 9, 2020.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–15216 Filed 7–14–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XS033]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Exempted Fishing Permits

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

ACTION: Notice of receipt of an application for exempted fishing permit; request for comments.

SUMMARY: NMFS announces the receipt of an application for an exempted fishing permit (EFP) from the University of Georgia Marine Extension and Georgia Sea Grant. If granted, the EFP would authorize the applicant to deploy modified black sea bass pots with Acoustic Subsea Buoy Retrieval Systems (ASBRS) in Federal waters off Georgia. The project would examine the potential usefulness of the ASBRSs for use in the black sea bass pot component for the commercial sector of the snapper-grouper fishery while minimizing impacts to protected species.

DATES: Written comments must be received on or before August 14, 2020.

ADDRESSES: You may submit comments on the application, identified by ''NOAA–NMFS–2020–0090'' by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0090,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Frank Helies, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the application and may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/southeast/black-sea-bass-pot-pilot-project-exempted-fishing-permit-application/.*

FOR FURTHER INFORMATION CONTACT: Frank Helies, 727–824–5305; email: *frank.helies@noaa.gov.*

SUPPLEMENTARY INFORMATION: The EFP is requested under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

Currently, vertical end lines and buoys, such as those utilized with black sea bass pots in the South Atlantic, present an entanglement risk to the North Atlantic right whale, a species that is listed as endangered under the Endangered Species Act (ESA) and that annually migrates and in the winter calves off the coast of Georgia in Federal and state waters. ASBRSs are a type of fishing gear that allows fish traps, including black sea bass pots, buoys, and their retrieval devices to be stored at depth until triggered for retrieval at the surface. These gear systems allow for trap and pot buoys and vertical lines to exist in the water column for minutes instead of hours or days, as they are activated via acoustic release only when fishers are present. As described in the application, the applicant believes that adaptation of ASBRSs or ''ropeless'' systems for black sea bass pot fishing in the South Atlantic could reduce the risk to these whales and other marine animals that are subject to entanglements from vertical lines and buoys.

If granted, the EFP would exempt limited fishing gear testing activities from certain regulations for the black sea bass pot component for the commercial sector of the South Atlantic snapper-grouper fishery, specifically gear identification at 50 CFR 622.177(a)(4), the sea bass pot configuration restriction at 50 CFR 622.189(b), and restrictions and requirements for sea bass pot buoy line marking at 50 CFR 622.189(g).

The applicant seeks an EFP to determine the following: If the ASBRS gear will show a greater than 99 percent successful deployment and retrieval rate; if ASBRS gear significantly increases the time and/or expense for gear retrieval and recovery versus the current fishing method such that it might affect profitability; if ASBRS gear significantly increases time and/or expense for the repacking of gear for redeployment versus the current fishing method such that it might affect profitability; and if bycatch rates for the modified black sea bass pot fishing configuration described below are greater than those for the traditional single pots.

Under the EFP, the applicant would collect data through an ongoing collaborative effort among different ASBRS manufacturers and fishery industry partners. In addition to this EFP request for exemption from Magnuson-Stevens Act regulations, the applicant would consult with NMFS to ensure the EFP would be consistent with North Atlantic right whale conservation measures currently in place through the ESA and Marine Mammal Protection Act. Fishers participating in this project would self-fund the trial and would keep and sell all catch lawfully harvested by black sea bass pots. The proposed testing area has an approximate perimeter of 87 nm and an area of 501 nm in Federal waters 10 to 32 nm off Townsend, Georgia. Testing would occur in Federal waters in depths between 10 and 30 m. The proposed testing area is outside the November 1 through April 30 area prohibition on the use of black sea bass pots. The testing would not occur in special management zones listed in 50 CFR 622.182((a)(l)(i) and (ii)) or the North Atlantic Right Whale Critical Habitat Area.

Black sea bass pots would be fished as singles with a traditional configuration (control pots) during August and September 2020. The control pots would yield data relative to the time used to retrieve and rebait traditional black seas bass pots that are fished per current regulations. Experimental configurations of black sea bass pots (described below) would be fished without vertical buoy lines on live bottom in the vicinity with the control pots. Using the ASBRS, the applicant would utilize virtual gear marking of the pots (marking of gear deployment location with chartplotters, GPS, and manufacturer-provided software). The applicant would also evaluate the feasibility of use of various virtual gear marking systems and share the results with fishery management partners.

Each pot deployment (ASBRS and control combined) under the EFP would be limited to 35 total pots with up to

300 gear hauls, with an average soak time of 90–120 minutes per configuration. Over the period of the EFP, the applicant expects to conduct 5 days total of testing in August and September 2020. The applicant intends to collect data from 90 traditional black sea bass pot deployments and 270 ASBRS gear deployments.

EFP Black Sea Bass Pot Configurations

Under the EFP, four regulation-sized pots would be connected together with wire connecting clips or zip ties so that only one ASBRS gear device is needed to retrieve four connected pots. Each pot would have the standard black sea bass pot single entrance and would possess one back panel of 2-inch (5.1-cm) uniform mesh. The connected four traps would test both one and two single entrances (on adjacent sides of single traps to replace the allowable two opposite entrances) to four regulation-sized trap interiors and would otherwise comply with the requirements for black sea bass pot dimensions and construction in the South Atlantic. This experimental gear design of the four connected pots is not a chevron-style fish trap, it is standard black sea bass pots connected to adjacent standard black sea bass pots. The goal of this modification is to examine ways to reduce procurement and implementation costs associated with the number of required ASBRSs to fish 35 pots.

The control traps used in the EFP would also be black sea bass pots, with a uniform back panel mesh size of 2-inch (5.1-cm) or greater, and a uniform all over mesh size on remaining sides of 1.5 inches (3.8 cm) or greater. A four pot trawl of single standard black sea bass pot gear would be deployed to compare the catchability between the two configurations.

EFP Gear Markings

Two of the technologies that would be used in the EFP utilize lift bags and buoys and are therefore unable to be line-marked as they do not incorporate line into their design. For the other technologies being tested under the EFP, all buoy lines on ASBRS gear types that use stored line would be marked in accordance with the most recent requirements per the Atlantic Large Whale Take Reduction Plan and Federal regulations, and would have weak links with a maximum breaking strength of 600 lb (272 kg), 1,700 lb (771 kg) maximum breaking strength sleeves, and line with a breaking strength of less than 2,200 lb (998 kg). These systems that incorporate line would only be fished inshore of the seasonal closure area of the commercial black sea bass pot component of the snapper-grouper fishery (50 CFR 622.183(b)(6)(i) and (ii)).

EFP Buoy Line

Six of the eight currently available ASBRS devices require the use of a line for retrieval that is contained and stored at depth by a line management system. The other two release devices do not use line, but instead, utilize the inflation of either a lift bag or inflatable buoy to pull a lead trap to the surface. The styles of line storage vary with device design and includes square, rectangular, domed, circular, and conical cages, oyster mesh bags, canisters, and spools. These have been successfully used in trials and testing in a variety of active fishing operations in the United States and worldwide.

Four of the ASBRS devices in the EFP require floating line to return the buoy or buoys to the surface for retrieval. Currently, the average time for appearance of buoys at depths greater than 100 ft (30.5 m) is approximately 3 minutes. Retrieval generally takes less than 2 minutes, which means that any floating line would be at the surface for less than 5 minutes, and during which time the fishing vessel would be within 20–30 ft (6.1–9.1 m) of the line. Two of the release devices do not incorporate line longer than 10 ft (3.1 m) in their design, and two devices use a harness that clips to the pot. The remaining devices use less than 150 ft (45.7 m) of line which would be stowed inside either a bag or on a spool. Sinking line cannot be used for any ASBRS as it would create a negatively buoyant strain on the buoys and not effectively allow for their return to the surface. All of the ASBRSs with a line storage system would need to be attached between the trap and the buoy. If necessary, several of the ASBRSs may also require a small anchor or weight to be attached between the pot and line-storage device or buoy in areas with higher current to keep them from fouling in the pot, as well as to ensure they are not dragged from their intended deployment area. For lift bag and buoy systems, the actual systems would be secured between the pot and the buoy/bag.

NMFS finds the application warrants further consideration based on a preliminary review. Possible conditions the agency may impose on the permit, if granted, include but are not limited to, a prohibition on conducting fishing gear testing within marine protected areas, marine sanctuaries, special management zones, or areas where they might interfere with managed fisheries without additional authorization. Additionally, NMFS may require special protections for ESA-listed species and designated critical habitat, and may require particular gear markings. A final decision on issuance of the EFP will depend on NMFS' review of public comments received on the application, consultations with the appropriate fishery management agency of the affected state, the South Atlantic Fishery Management Council, and the U.S. Coast Guard, and a determination that the activities to be taken under the EFP are consistent with all applicable laws.

Authority: 16 U.S.C 1801 *et seq.*

Dated: July 9, 2020.

Ngagne Jafnar Gueye,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–15192 Filed 7–14–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA242]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to National Wildlife Refuge Complex Research, Monitoring, and Maintenance Activities in Massachusetts

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

ACTION: Notice; request for comments on proposed Renewal incidental harassment authorization.

SUMMARY: NMFS received a request from the U.S. Fish and Wildlife Service (USFWS) for the Renewal of their currently active incidental harassment authorization (IHA) to take marine mammals incidental to conducting biological research, monitoring, and maintenance at the Eastern Massachusetts (MA) National Wildlife Refuge Complex (Complex). These activities are identical to those covered in the current authorization. Pursuant to the Marine Mammal Protection Act (MMPA), prior to issuing the currently active IHA, NMFS requested comments on both the proposed IHA and the potential for renewing the initial authorization if certain requirements were satisfied. The Renewal requirements have been satisfied, and NMFS is now providing an additional 15-day comment period to allow for any additional comments on the proposed

Renewal not previously provided during the initial 30-day comment period.

DATES: Comments and information must be received no later than July 30, 2020.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Written comments should be submitted via email to *ITP.Fowler@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. Attachments to comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the original application, Renewal request, and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as ''mitigation measures''). Monitoring and reporting of such takings are also required. The meaning of key terms such as ''take,'' ''harassment,'' and ''negligible impact'' can be found in section 3 of the MMPA (16 U.S.C. 1362) and the agency's regulations at 50 CFR 216.103.

NMFS' regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed one year for each reauthorization. In the notice of proposed IHA for the initial authorization, NMFS described the circumstances under which we would consider issuing a Renewal for this activity, and requested public comment on a potential Renewal under those circumstances. Specifically, on a case-by-case basis, NMFS may issue a one-time one-year Renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical, or nearly identical, activities as described in the Description of Specified Activities and Anticipated Impacts section of this notice is planned or (2) the activities as described in the Description of Specified Activities and Anticipated Impacts section of this notice would not be completed by the time the IHA expires and a Renewal would allow for completion of the activities beyond that described in the Dates and Duration section of the notice of proposed IHA for the initial IHA, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed Renewal IHA effective date (recognizing that the Renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA).
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested Renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for Renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed Renewal. A description of the Renewal process may be found on our website at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals.* Any comments received on the potential Renewal, along with relevant comments on the initial IHA, have been considered in the development of this proposed IHA Renewal, and a summary of agency responses to applicable comments is included in this notice. NMFS will consider any additional public comments prior to making any final decision on the issuance of the requested Renewal, and agency responses will be summarized in the final notice of our decision.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA Renewal) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that

would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA Renewal qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA Renewal request.

History of Request

On June 12, 2019, NMFS issued an IHA to the USFWS to take marine mammals incidental to research, monitoring, and maintenance activities within the Complex (84 FR 32415; July 8, 2019), effective from June 12, 2019 through June 11, 2020. On May 22, 2020, NMFS received an application for the Renewal of that initial IHA. As described in the application for Renewal IHA, the activities for which incidental take is requested are identical to those covered in the initial authorization. As required, the applicant also provided a preliminary monitoring report (available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities*) which confirms that the applicant has implemented the required mitigation and monitoring, and which also shows that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted.

NMFS has previously issued two additional IHAs to the USFWS for similar activities (82 FR 3738, January 12, 2017; 83 FR 19236, May 2, 2018).

Description of the Specified Activities and Anticipated Impacts

The Complex is comprised of eight refuges, including its three coastal refuges: Monomoy National Wildlife Refuge (NWR), Nantucket NWR, and Nomans Land Island (Nomans) NWR in eastern MA. The USFWS conducts ongoing biological tasks for refuge purposes at the Complex. The 2017 and 2018 IHAs covered shorebird and seabird nest monitoring and research, roseate tern (*Sterna dougallii*) staging counts and resighting, red knot (*Calidris canutus*) stopover study, northeastern beach tiger beetle (*Cicindela dorsalis*) census, and coastal shoreline change survey at Monomoy, Nantucket, and Nomans NWRs. Under the 2019 IHA (the initial IHA), the USFWS conducted identical seabird and shorebird research and monitoring activities, and also conducted New England cottontail (*Sylvilagus transitionalis*) reintroduction on Nomans NWR and protection of seal haulout areas at Nantucket NWR.

As in the initial authorization, NMFS anticipates that take, by Level B harassment only, of gray seals (*Halichoerus grypus atlantica*) and harbor seals (*Phoca vitulina concolor*) could result from the specified activities (84 FR 32415; July 8, 2019).

Detailed Description of the Activity

A detailed description of the USFWS proposed seabird and shorebird research and monitoring activities can be found in the **Federal Register** notice of proposed IHA for the 2018 IHA (83 FR 9483; March 6, 2018). A detailed description of the New England cottontail reintroduction and seal haul out protection activities can be found in the **Federal Register** notice of proposed IHA for the initial (2019) IHA (84 FR 18259, April 30, 2019). The locations (as described in the Specific Geographic Region section of the initial IHA), timing, amount, and nature of the specified activities are identical to those described in the previous notices.

The proposed IHA Renewal would be effective from the date of issuance through June 11, 2021.

Description of Marine Mammals

A description of the marine mammals in the area of the activities for which authorization of take is proposed here, including information on abundance, status, distribution, and hearing, may be found in the **Federal Register** notice of the proposed IHA for the 2018 IHA (83 FR 9483; March 6, 2018). Summary information is available in the **Federal Register** notices of the proposed and final initial authorization (84 FR 18259, April 30, 2019; 84 FR 32415, July 8, 2019). NMFS has reviewed the monitoring data from the initial IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific literature, and determined that neither this nor any other new information affects which species or stocks have the potential to be affected or the pertinent information in the Description of the Marine Mammals in the Area of Specified Activities contained in the supporting documents for the initial IHA.

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which take is proposed here may be found in the **Federal Register** notice of the proposed IHA for the 2018 IHA (83 FR 9483; March 6, 2018). Summary information is available in the **Federal Register** notices of the proposed and final initial authorization (84 FR 18259, April 30, 2019; 84 FR 32415, July 8, 2019). NMFS has reviewed the monitoring data from the initial IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific literature, and determined that neither this nor any other new information affects our initial analysis of impacts on marine mammals and their habitat.

Estimated Take

A detailed description of the methods and inputs used to estimate authorized take is found in the **Federal Register** notice of the proposed IHA for the 2018 IHA (83 FR 9483; March 6, 2018). Summary information is available in the **Federal Register** notices of the proposed and final initial authorization (84 FR 18259, April 30, 2019; 84 FR 32415, July 8, 2019). All estimated take is expected to be in the form of Level B harassment. The methods of estimating take for this proposed IHA Renewal are identical to those used in the initial IHA (*i.e.,* by multiplying the maximum number of seals estimated to be present at each location by the number of events at each location that may result in disturbance). Specifically, the frequency of activities and marine mammal occurrence applicable to this authorization remain unchanged from the previously issued IHA (see Table 1). Similarly, the stocks taken, methods of take, and types of take remain unchanged from the previously issued IHA, as do the number of takes, which are indicated below in Table 2.

The total estimated gray seal takes are presented in Table 1.

TABLE 1—ESTIMATED NUMBER OF GRAY SEAL TAKES (BY LEVEL B HARASSMENT) PER ACTIVITY AT MONOMOY, NANTUCKET, AND NOMANS NWRS

Activity	Takes per event	Events per activity	Total takes
Shorebird and Seabird Monitoring & Research.	1000 (Monomoy), 50 (Nantucket), 10 (Nomans).	34 (Monomoy), 8 (Nantucket), 3 (Nomans).	34,430

TABLE 1—ESTIMATED NUMBER OF GRAY SEAL TAKES (BY LEVEL B HARASSMENT) PER ACTIVITY AT MONOMOY, NANTUCKET, AND NOMANS NWRS—Continued

Activity	Takes per event	Events per activity	Total takes
Roseate Tern Staging Counts & Re-sighting.	10 (Monomoy), 10 (Nantucket)	6 (Monomoy), 4 (Nantucket)	100
Red Knot Stopover Study	250 (Monomoy), 150 (Cape Cod)	5 (Monomoy), 5 (Cape Cod)	2,000
Northeastern Beach Tiger Beetle Census	750 (Monomoy)	3 (Monomoy)	2,250
Coastal Shoreline Change Survey	500 (Monomoy)	1 (Monomoy)	500
New England Cottontail Introduction	10 (Nomans)	20 (Nomans)	200
Seal Haul Out Protection	25 (Nantucket)	10 (Nantucket)	250
Total takes			39,730

Estimated take of harbor seals was estimated using methods identical to the initial IHA (*i.e.,* by estimating five percent of gray seal takes). Total proposed takes of gray seals and harbor seals are shown in Table 2.

TABLE 2—TOTAL PROPOSED TAKE OF MARINE MAMMALS, RELATIVE TO POPULATION SIZE

Species	Estimated take by Level B harassment	Stock abundance	Percent (comparison of instances of take to stock abundance)
Gray seal	39,730	[a] 27,131 [b] (451,131)	146 (8.81)
Harbor seal	1,987	75,834	2.62

[a] Abundance in U.S. waters (Hayes *et al.,* 2018).
[b] Overall Western North Atlantic stock abundance (Hayes *et al.,* 2018).

Based on the stock abundance estimate presented in the 2017 Stock Assessment Report, the proposed take number of gray seals exceeds the number of gray seals in U.S. waters (Table 2; Hayes *et al.,* 2018). However, actual take may be slightly less if animals decide to haul out at a different location for the day or if animals are foraging at the time of the survey activities. The number of individual seals taken is also assumed to be less than the take estimate since these species show high philopatry (Waring *et al.,* 2016; Wood *et al.,* 2011). We expect the take numbers to represent the number of exposures (*i.e.,* instances of take), but assume that the same seals may be behaviorally harassed over multiple days, and the likely number of individual seals that may be harassed would be less. In addition, this project occurs in a small portion of the overall range of the Northwest Atlantic population of gray seals. While there is evidence of haulout site philopatry, resights of tagged and branded animals and satellite tracks of tagged animals show movement of individuals between the United States and Canada (Puryear *et al.,* 2016). The percentage of time that individuals are resident in U.S. waters is unknown (NMFS 2017). Genetic evidence provides a high degree of certainty that the Western North Atlantic stock of gray seals is a single stock (Boskovic *et al.,* 1996; Wood *et al.,* 2011). Thus, although the U.S. stock estimate is only 27,131, the overall stock abundance of animals in United States and Canadian waters is 451,131. The gray seal take estimate for this project represents less than 9 percent of the overall Western North Atlantic stock abundance (Table 2) if every separate instance of take were assumed to accrue to a different individual, and because this is not the case, the percentage is likely significantly lower.

Description of Proposed Mitigation, Monitoring and Reporting Measures

The proposed mitigation, monitoring, and reporting measures included as requirements in this authorization are identical to those included in the **Federal Register** notice announcing the issuance of the initial IHA (84 FR 32414; July 8, 2020), and the discussion of the least practicable adverse impact included in that notice remains accurate. The following measures are proposed for this renewal:

Time and Frequency

The USFWS would conduct all proposed research and monitoring activities throughout the course of the year between April 1 and November 30, outside of the seasons of highest seal abundance and pupping at the Complex. Closure of beaches used by seals may occur year-round at Nantucket NWR.

Vessel Approach and Timing Techniques

The USFWS would ensure that its vessels approach beaches with pinniped haul outs so as to not disturb marine mammals as is most practical. To the extent possible, the vessel would approach the beaches in a slow and controlled approach, as far away as possibly from haulouts to prevent or minimize flushing. Staff would also avoid or proceed cautiously when operating boats in the direct path of swimming seals that may be present in the area.

Avoidance of Acoustic Impacts From Cannon Nets

Cannon nets have a measured source level (SL) of 128 decibels (dB) at one meter (m) (estimated based on a measurement of 98.4 dB at 30 m; L. Niles, pers. comm., December 2016); however, the sound pressure level (SPL) is expected to be less than the thresholds for airborne pinniped disturbance (*e.g.,* 90 dB for harbor seals, and 100 dB for all other pinnipeds) at 80 yards (73 meters) from the source. The USFWS proposes to stay at least 100 m from all pinnipeds if cannon nets are to be used for research purposes.

Avoidance of Visual and Acoustic Contact With People

The USFWS would instruct its members and research staff to avoid making unnecessary noise and not allow themselves to be seen by pinnipeds whenever practicable. USFWS staff would stay at least 50 yards (46 meters) from hauled out pinnipeds, unless it is absolutely necessary to approach seals closer, or potentially flush a seal, in order to continue conducting endangered species conservation work. When disturbance is unavoidable, staff will work quickly and efficiently to minimize the length of disturbance. Researchers and staff will do so by proceeding in a slow and controlled manner, which allows for the seals to slowly flush into the water. Staff will also maintain a quiet working atmosphere, avoiding loud noises, and using hushed voices in the presence of hauled out pinnipeds. Pathways of approach to the desired study or nesting site will be chosen to minimize seal disturbance if an activity event may result in the disturbance of seals. USFWS staff will scan the surrounding waters near the haulouts, and if predators (*i.e.,* sharks) are seen, seals will not be flushed by USFWS staff.

Marine Mammal Monitoring

The USFWS will monitor seals as project activities are conducted. Proposed monitoring requirements in relation to the USFWS's proposed activities would include species counts, numbers of observed disturbances, and descriptions of the disturbance behaviors during the research activities, including location, date, and time of the event. In addition, the USFWS would record observations regarding the number and species of any marine mammals either observed in the water or hauled out. Behavior of seals will be recorded on a three point scale: 1 = alert reaction, not considered harassment; 2 = moving at least two body lengths, or change in direction greater than 90 degrees; 3 = flushing (Table 3). USFWS staff would also record and report all observations of sick, injured, or entangled marine mammals on Monomoy NWR to the International Fund for Animal Welfare (IFAW) marine mammal rescue team, and will report to NOAA if injured seals are found at Nantucket NWR and Nomans NWR. Tagged or marked marine mammals will also be recorded and reported to the appropriate research organization or Federal agency, as well as any rare or unusual species of marine mammal. Photographs will be taken when possible. This information will be incorporated into a report for NMFS at the end of the season. The USFWS will also coordinate with any university, state, or Federal researchers to attain additional data or observations that may be useful for monitoring marine mammal usage at the activity sites.

TABLE 3—LEVELS OF PINNIPED BEHAVIORAL DISTURBANCE

Level	Type of response	Definition
1	Alert	Seal head orientation or brief movement in response to disturbance, which may include turning head towards the disturbance, craning head and neck while holding the body rigid in a u-shaped position, changing from a lying to a sitting position, or brief movement of less than twice the animal's body length.
2*	Movement	Movements in response to the source of disturbance, ranging from short withdrawals at least twice the animal's body length to longer retreats over the beach, or if already moving a change of direction of greater than 90 degrees.
3*	Flush	All retreats (flushes) to the water.

*Only observations of disturbance Levels 2 and 3 are recorded as takes.

If at any time injury, serious injury, or mortality of the species for which take is authorized should occur, or if take of any kind of other marine mammal occurs, and such action may be a result of the USFWS's activities, the USFWS would suspend activities and contact NMFS immediately to determine how best to proceed to ensure that another injury or death does not occur and to ensure that the applicant remains in compliance with the MMPA.

Reporting

The USFWS would submit a draft report to NMFS Office of Protected Resources no later than 90 days after the expiration of this authorization. The report will include a summary of the information gathered pursuant to the monitoring requirements set forth in the proposed IHA. The USFWS will submit a final report to NMFS within 30 days after receiving comments from NMFS on the draft report. If the USFWS receives no comments from NMFS on the draft report, NMFS will consider the draft report to be the final report.

Public Comments

As noted previously, NMFS published a notice of a proposed IHA (84 FR 18259; April 30, 2019) and solicited public comments on both our proposal to issue the initial IHA for the USFWS's seabird and shorebird research and monitoring activities and on the potential for a Renewal IHA, should certain requirements be met.

All public comments were addressed in the notice announcing the issuance of the initial IHA (84 FR 32415; July 8, 2019). Below, we describe how we have addressed, with updated information where appropriate, any comments received that specifically pertain to the Renewal of the 2019 IHA.

Comment: The Marine Mammal Commission (Commission) questioned whether the public notice provisions for IHA renewals fully satisfy the public notice and comment provision in the MMPA and discussed the potential burden on reviewers of reviewing key documents and developing comments quickly. Additionally, the Commission recommended that NMFS use the IHA Renewal process sparingly and selectively for activities expected to have the lowest levels of impacts to marine mammals and that require less complex analysis.

Response: The Commission has submitted this comment multiple times, and NMFS has responded multiple times, including, for example, more recently in the notice of issuance of an IHA to Ørsted Wind Power LLC (84 FR 52464, October 2, 2019), and we refer the Commission to that response. We also include NMFS' original response to the comment received on the 2019 USFWS proposed IHA here:

NMFS has taken a number of steps to ensure the public has adequate notice, time, and information to be able to comment effectively on Renewal IHAs within the limitations of processing IHA applications efficiently. **Federal Register** notices for the proposed initial IHAs identified the conditions under which a one-year Renewal IHA might be appropriate. This information is presented in the Request for Public Comments section of the **Federal Register** notice of the initial proposed IHA (84 FR 18259; April 30, 2019) and

thus encourages submission of comments on the potential of a one-year renewal as well as the initial IHA during the 30-day comment period. In addition, when we receive an application for a Renewal IHA, we will publish notice of the proposed IHA Renewal in the **Federal Register** and provide an additional 15 days for public comment, making a total of 45 days of public comment. We also directly contact all commenters on the initial IHA by email, phone, or, if the commenter did not provide email or phone information, by postal service to provide them the opportunity to submit any additional comments on the proposed Renewal IHA. Where the commenter has already had the opportunity to review and comment on the potential for a Renewal in the initial proposed IHA for these activities, the abbreviated additional comment period is sufficient for consideration of the results of the preliminary monitoring report and new information (if any) from the past year.

NMFS also strives to ensure the public has access to key information needed to submit comments on a proposed IHA, whether an initial IHA or a Renewal IHA. The agency's website includes information for all projects under consideration, including the application, references, and other supporting documents. Each **Federal Register** notice also includes contact information in the event a commenter has questions or cannot find the information they seek.

For more information, NMFS has published a description of the Renewal process on our website (available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals*).

Preliminary Determinations

The seabird and shorebird research and monitoring activities proposed by the USFWS are identical to those analyzed in the initial IHA, as are the expected number of days of activity, the method of taking, and the effects of the action. The potential effects of the USFWS's activities are limited to Level B harassment in the form of behavioral disturbance. In analyzing the effects of the activities in the initial IHA, NMFS determined that the USFWS's activities would have a negligible impact on the affected species or stocks and that the authorized take numbers of each species or stock were small relative to the relevant stocks (*e.g.,* less than 9 percent of all stocks). The numbers of marine mammals proposed to be taken in this authorization are identical to those authorized in the initial IHA. The mitigation measures and monitoring and reporting requirements as described above also are identical to the initial IHA.

NMFS has preliminarily concluded that there is no new information suggesting that our analysis or findings should change from those reached for the initial IHA. Based on the information and analysis contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) USFWS's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and; (5) appropriate monitoring and reporting requirements are included.

Endangered Species Act (ESA)

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Proposed Renewal IHA and Request for Public Comment

As a result of these preliminary determinations, NMFS proposes to issue a Renewal IHA to the USFWS for conducting research and monitoring activities at the Complex from the date of issuance through June 11, 2021, provided the previously described mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed and final initial IHA can be found at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

We request comment on our analyses, the proposed Renewal IHA, and any other aspect of this notice. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

Dated: July 9, 2020.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–15199 Filed 7–14–20; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA116]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Gastineau Channel Historical Society Sentinel Island Moorage Float Project, Juneau, Alaska

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to the Gastineau Channel Historical Society (GCHS) to incidentally harass, by Level B harassment only, marine mammals during construction activities associated with the Sentinel Island Moorage Float project near Juneau, Alaska.

DATES: This Authorization is effective from July 15, 2020 to September 20, 2020.

FOR FURTHER INFORMATION CONTACT: Dwayne Meadows, Ph.D., Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth.

The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On 24 October 2019, NMFS received a request from GCHS for an IHA to take marine mammals incidental to Sentinel Island Moorage Float project near Juneau, Alaska. The application was deemed adequate and complete on February 7, 2020. GCHS's request is for take of seven species (consisting of eight stocks) of marine mammals by Level B harassment and/or Level A harassment. Neither GCHS nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of the Specified Activity

Overview

The project consists of the construction of an access float to more easily access Sentinel Island within Favorite Channel/Lynn Canal near Juneau, Alaska. GCHS would install a pile supported marine float with a metal gangway spanning from the float to a timber platform on Sentinel Island. The project includes the following in-water components: Driving six 24-inch diameter steel pipe piles to support the float and seaward end of the gangway. Pile driving would be by vibratory pile driving to install the piles until down-the-hole (DTH) drilling is needed to rock socket the piles. Impact pile driving will only be used for piles that encounter soils too dense to penetrate with the vibratory equipment, which is not expected. A detailed description of the planned project is provided in the **Federal Register** notice for the proposed IHA (85 FR 18196; April 1, 2020). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

A notice of NMFS's proposal to issue an IHA to GCHS was published in the **Federal Register** on April 1, 2020 (85 FR 18196). That notice described, in detail, GCHS's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. During the 30-day public comment period, NMFS received comments from Defenders of Wildlife (Defenders). A comment letter from the Marine Mammal Commission (Commission) was received pursuant to the Commission's authority to recommend steps it deems necessary or desirable to protect and conserve marine mammals (16 U.S.C. 1402). We are obligated to respond to the Commission's recommendations within 120 days, and we do so below.

Comment: Defenders suggested that an additional local location where Steller sea lions aggregate is Poundstone Rock buoy which is 1.6 miles (2.6 km) from the southern end of Sentinel Island. They assert the buoy is in the Level B harassment zone and request we confirm this and state if take would occur at this location. They also request Protected Species Observers (PSOs) be notified of this resting area.

Response: We thank Defenders for noting this additional location. Poundstone Rock and buoy are several hundred meters to the west of the level B harassment zone so animals resting there would not be taken as a result of this project.

Comment: Defenders requests we ground truth the data of Wade *et al.* (2016) with regard to the proportion of humpback whales of the Endangered Species Act (ESA) listed Mexico Distinct Population Segment (DPS) in southeast Alaska.

Response: We thank Defenders for their comments. Our obligation under the MMPA is to issue incidental take authorizations for stocks of marine mammals (or species when stocks have not been assigned). The relevant stock in this area is the Central North Pacific stock. The DPSs created under the ESA are only relevant for regulatory actions under that law. NMFS's Alaska Regional office conducted an ESA Section 7 consultation on this IHA which concluded that NMFS authorization of take of humpback whales under the MMPA is not likely to jeopardize continued existence of humpback whales (or any other ESA-listed species), and is not likely to destroy or adversely modify any critical habitat (specifically, western DPS Steller sea lion).

Comment: Defenders also encourages us to reference and discuss a new paper by Southall *et al.* (2019) regarding marine mammal noise exposure criteria.

Response: We appreciate Defenders comment. NMFS has reviewed the Southall *et al.* (2019) paper in the context of NMFS' 2018 Revised Technical Guidance. The paper recommends the same thresholds and weighting functions as NMFS' 2018 Technical Guidance and no changes are necessary in our analysis.

Comment: The Commission recommends that NMFS convey any concerns of local native Alaska communities in the **Federal Register** notices for draft and final authorizations regarding subsistence use and how those concerns will be addressed by either the applicant or NMFS.

Response: We agree with the Commission. In order to issue an IHA, NMFS must find that the specified activity will not have an ''unmitigable adverse impact'' on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103. Sealaska Heritage Institute requested, and GCHS indicated that it would require the contractor to provide public notice 7 days in advance of the project and again 2 days before construction commences in the local media and to post information signage on the board at the Amalga Harbor boat launch 7 days prior to commencement of construction activities.

Comment: The Commission recommends that for all authorizations involving DTH drilling, including GCHS's final IHA, NMFS (1) use source level data from Denes *et al.* (2019), its Level A harassment thresholds for impulsive sources, and the relevant expected operating parameters to estimate the extents of the Level A harassment zones, (2) use source level data from Denes *et al.* (2016) and its Level B harassment threshold of 120-decibels (dB) for continuous sources to estimate the extents of the Level B harassment zones, (3) ensure the shut-down zones are reasonable to minimize unnecessary delays and enable the activities to be completed in a timely manner, and (4) ensure that the numbers of Level A and B harassment takes are sufficient based on the resulting zones, including in GCHS's case the Level A harassment takes.

Response: NMFS acknowledges that DTH piling operations can, but may not always, include both impulsive and continuous noise components. The

limited available data show that the specific acoustic characteristics of any particular DTH piling operation can vary significantly, based on the extent of the continuous non-pulse acoustic components of the drilling/pumping and the impulsive acoustic components of the hammering, as well as the nature of the environment (especially bottom characteristics). Currently, given the potential variation in the acoustic output from any specific operation and the limited in situ measurements of DTH piling available, NMFS is taking a conservative approach until more data are available. Specifically, we recommend estimating the potential impulsive components (and using the associated thresholds) of the operations for the purposes of predicting Level A harassment and estimating the potential continuous components (and using the associated threshold) for the purposes of predicting Level B harassment. As recommended, we have used the Denes *et al.* (2016) source level as a proxy source level for the purposes of the Level B harassment assessment. For the purposes of the Level A harassment assessment, while using Denes *et al.* (2019) may be more appropriate for larger pile sizes, Denes *et al.* (2016), which shows a single strike source level of 154 dB SEL, is the most relevant and appropriate source level for the 24-inch pile size of this project.

We have recently received new analyses and data that provide us three references for source levels. For the 24-inch pile size of this project the most relevant source level is Denes *et al.* (2016), which new analyses show has a single strike source level of 154 dB (Sound Exposure Level) SEL.

We note that it is not a simple matter to estimate the strikes per pile needed as input to calculate Level A harassment isopleths. DTH equipment varies significantly in hammer rates both within and across hole sizes. For example, we note that the Commission's recommendation of 7 to 10 strikes per second is far below values we know to be applicable for equipment of this size (*e.g.,* the equipment used at Ward Cove (85 FR 12523; March 3, 2020), operated at 15 strikes per second). We further note that the Commission is under the impression that the appropriate pulse duration for DTH hammering is 100 milliseconds (msec), a standard value applied to impact hammers. There is no reason to assume DTH hammers have a similar pulse duration, and in fact Denes *et al.* (2019) provided data on pulse durations. We also note that Denes *et al.* (2019) used a 42-inch drill bit to drill much larger holes than the 24-inch drill holes of this project. The larger drill bits likely create louder sounds from the larger area of contact with rock, which means that the Level A harassment zones would be overestimated to some degree for this project.

Finally, we have ensured that the shut-down zones are reasonable to minimize unnecessary delays and enable the activities to be completed in a timely manner, and that the numbers of Level A and B harassment takes are sufficient based on the new zones.

Comment: The Commission recommends that NMFS encourage action proponents to provide the necessary operational information and characteristics for DTH drilling, use consistent terminology regarding DTH drilling in all relevant applications, and use consistent terminology in all future **Federal Register** notices and draft and final authorizations that involve DTH drilling.

Response: We agree with the Commission that as knowledge of the variety of DTH methods and uses grows, more information from applicants on operational information and characteristics of DTH drills, and more consistent terminology, is beneficial. We note that many applicants do not know exactly what DTH equipment they will use at the time of application and that DTH equipment appears to have more variable operational parameters than impact or pile driving. The lack of data on the extremes of these operational parameters for DTH systems makes implementing even conservative assumptions challenging. The Commission could be of great service by helping to gather and publish the relevant information from literature and experts to increase our understanding of these systems.

Comment: The Commission recommends that NMFS require all applicants that propose to use a DTH hammer to install piles, including GCHS, to conduct in-situ measurements, ensure that signal processing is conducted appropriately, and adjust the Level A and B harassment zones accordingly.

Response: We will evaluate the need to require such measures for future projects on a case-by-case basis, though we acknowledge the general need for more data on these sources.

Comment: The Commission recommends that NMFS (1) ensure that take estimates for all proposed IHAs and rulemakings and for GCHS's final authorization abide by its policy that an individual marine mammal can be taken only once on a given day and specify that policy on its web page, (2) increase the haulout count from 134 to 849 seals based on the 95-percent CI for seals at CF13 and CF11 [Marine Mammal lab survey unit descriptors] and authorize at least 5,094 takes of harbor seals in the final authorization, and (3) specify that 849 individual seals could be taken and factor that number into the percentage of the stock taken and its small numbers determination.

Response: For the purposes of predicting and authorizing take, NMFS' general practice is to limit the enumeration of take of individual marine mammals to once per day and we plan to augment our application instructions on the web to indicate this. For the purposes of monitoring impacts, we clarify the difference between takes and potential daily number of observations that PSOs may or may not be able to attribute to single individuals throughout the course of a day. We disagree with the Commission that take be increased for unit CF11. Unit CF 11 is not within the level B harassment zone and the Commission provided no evidence that animals from CF11 enter the Level B harassment zone. CF12 and CF13 areas are larger than the project area so, regardless of whether animals from other areas move in and out, the total number of animals surveyed from those areas represent a conservative estimate of the maximum number of individuals that might be present and taken during the course of a day.

Comment: The Commission recommends that NMFS ensure GCHS keeps a running tally of the total takes, based on observed and extrapolated takes, for Level A and B harassment.

Response: We agree that the applicant must ensure they do not exceed authorized takes. A condition for extrapolation of the estimated takes by Level B harassment based on the number of observed exposures within the Level B harassment zone and the percentage of the Level B harassment zone that was not visible is included.

Comment: The Commission recommends that NMFS refrain from issuing renewals for any authorization and instead use its abbreviated **Federal Register** notice process. They further recommend that if NMFS uses renewals, we (1) stipulate in all **Federal Register** notices and authorizations that a renewal is a one-time opportunity and, (2) if NMFS refuses to stipulate a renewal being a one-time opportunity, explain why it will not do so. The Commission also claimed that NMFS' failure to address the Commission's comments and recommendations in the decision document runs counter to the requirements of the Administrative Procedures Act (APA).

Response: NMFS has changed their website and templates to reflect that Renewals are a one-time opportunity. Regarding the recommendation to refrain from using the Renewal process, NMFS does not agree with the Commission and, therefore, does not adopt the Commission's recommendation. NMFS has explained the rationale for this decision in multiple **Federal Register** notices (*e.g.,* 84 FR 52464; October 02, 2019), nonetheless, NMFS will also provide a separate detailed explanation of its decision within 120 days, as required by section 202(d) of the MMPA.

Comment: The Commission recommended that NMFS continue to include in all draft and final IHAs the explicit requirements to cease activities if a marine mammal is injured or killed during the proposed activities until NMFS reviews the circumstances involving any injury or death that has been attributed to the activities and determines what additional measures are necessary to minimize additional injuries or deaths.

Response: NMFS concurs with the Commission's recommendation as it relates to this IHA, and construction IHAs in general, and has added the referenced language to the Monitoring and Reporting section of this notice and the Reporting section of the issued IHA. We will continue to evaluate inclusion of this language in future IHAs.

Changes From the Proposed IHA to Final IHA

The vibratory pile driving source level for 16 inch piles from the U.S. Navy (2015) was corrected to 162 dB (SPL (root mean square) rms) from 161 dB in the proposed rule. We clarified the actual take is limited to one take per animal per day, and that calculations of total instances of sightings per day that may initially be made by observers cannot exceed more than 1 take per individual per day from the known population in the area (See Estimated Take section for revised description). The condition for extrapolation of the estimated takes by Level B harassment based on the number of observed exposures within the Level B harassment zone and the percentage of the Level B harassment zone that was not visible was inadvertently omitted in the proposed IHA **Federal Register** notice and is now included.

As discussed above in the Comments and Responses section, we are changing the approach to DTH hammering so that we estimate the potential impulsive components (using the associated thresholds) of the operations for the purposes of predicting Level A harassment and estimate the potential continuous components (using the associated threshold) for the purposes of predicting Level B harassment. We use the Denes *et al.,* (2016) source level of 154 dB single strike SEL as a proxy source level for the purposes of the Level A harassment assessment and continue to use the 166.2 dB RMS) source level for Level B calculations. As a result new Level A harassment zones (see Estimated Take section below) and shutdown zones (see Mitigation section below) are incorporated. These new zones are smaller than the existing zones for impact pile driving, and since the different pile driving activities are likely to occur on the same day, there is no change to estimated take. We add the explicit requirements to cease activities if a marine mammal is injured or killed during the proposed activities until NMFS reviews the circumstances to the Monitoring and Reporting section of this notice and the Reporting section of the issued IHA. Typographical errors were corrected.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/find-species*).

Table 1 lists all species with expected potential for occurrence in Juneau, Alaska and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2019). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. Alaska SARs (*e.g.,* Muto *et al.,* 2019). All values presented in Table 1 are the most recent available at the time of publication and are available in the draft 2019 SARs (Muto *et al.,* 2019).

TABLE 1—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF THE STUDY AREAS

Common name	Scientific name	Stock	ESA/MMPA status; Strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Physeteridae:						
Sperm whale	*Physeter macrocephalus*	North Pacific	-; N	N/A (see SAR, N/A, 2015), see text.	See SAR	4.4
Family Balaenopteridae (rorquals):						
Humpback Whale	*Megaptera novaeangliae*	Central North Pacific	-;N (Hawaii DPS)	10,103 (0.3, 7,890, 2006).	83	25
		Central North Pacific	T,D,Y (Mexico DPS)	3264	N/A	N/A

TABLE 1—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF THE STUDY AREAS—Continued

Common name	Scientific name	Stock	ESA/MMPA status; Strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Minke whale [4]	*Balaenoptera acutorostrata*	Alaska	-; N	N/A, see text	N/A	0
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Killer whale [5]	*Orcinus orca*	Alaska Resident	-; Y	2347	24	1
		Northern Resident		261	1.96	0
		West Coast transient		243	2.4	0
Family Phocoenidae (porpoises):						
Dall's porpoise [4]	*Phocoenoides dalli*	Alaska	-;N	83,400 (0.097, N/A, 1991).	N/A	38
Harbor porpoise	*Phocoena phocoena*	Southeast Alaska	-; Y	975 (2012)	8.9	34
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions):						
Steller sea lion	*Eumetopias jubatus*	Eastern U.S	-; N	41,638 (n/a; 41,638; 2015).	2,498	108
Steller sea lion	*Eumetopias jubatus*	Western U.S.	E,D,Y	54,268 (see SAR, 54,267, 2017).	326	247
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina richardii*	Lynn Canal/Stephens Passage.	-; N	9,478 (see SAR, 8,605, 2011).	155	50

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal SARs online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual mortality/serious injury (M/SI) often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[4] The most recent abundance estimate is >8 years old, there is no official current estimate of abundance available for this stock.

[5] NMFS has preliminary genetic information on killer whales in Alaska which indicates that the current stock structure of killer whales in Alaska needs to be reassessed. NMFS is evaluating the new genetic information. A complete revision of the killer whale stock assessments will be postponed until the stock structure evaluation is completed and any new stocks are identified'' (Muto, Helker *et al.* 2018). For the purposes of this IHA application, the existing stocks are used to estimate potential takes.

All species that could potentially occur in the proposed survey areas are included in Table 1. As described below, seven species (with eight managed stocks) temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have proposed authorizing it. Sperm whales are considered extra-limital and will not be considered further.

A detailed description of the species likely to be affected by the project, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (85 FR 18196; April 1, 2020); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions. Please also refer to NMFS' website (*https://www.fisheries.noaa.gov/find-species*) for generalized species accounts.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from GCHS's construction activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the survey area. The notice of proposed IHA (85 FR 18196; April 1, 2020) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from GCHS's activities on marine mammals and their habitat. That information and analysis is incorporated by reference into this final IHA determination and is not repeated here; please refer to the notice of proposed IHA (85 FR 18196; April 1, 2020).

Estimated Take

This section provides an estimate of the number of incidental takes authorized through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of the acoustic source (*i.e.,* vibratory or impact pile driving or DTH drilling) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for mysticetes, high frequency species and pinnipeds because predicted auditory

injury zones are larger than for mid-frequency species. Auditory injury is unlikely to occur for mid-frequency species and otariids. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the take estimate.

Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur Permanent Threshold Shift (PTS) of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 microPascal (μPa) (rms) for continuous (*e.g.,* vibratory pile-driving, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* impact pile driving) or intermittent (*e.g.,* scientific sonar) sources.

GCHS's proposed activity includes the use of continuous (vibratory pile-driving and DTH drilling) and impulsive (impact pile-driving and DTH drilling) sources, and therefore the 120 and 160 dB re 1 μPa (rms) thresholds are applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). GCHS's activity includes the use of impulsive (impact pile-driving) sources.

These thresholds are provided in Table 2. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 2—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

	PTS onset acoustic thresholds * (received level)	
Hearing group	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	Cell 2: $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	Cell 4: $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	Cell 6: $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	Cell 7: $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	Cell 8: $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	Cell 9: $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	Cell 10: $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μPa, and cumulative sound exposure level (L_E) has a reference value of 1μPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level (SEL) thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient. For DTH, as discussed above, we now estimate the potential impulsive components (using the associated thresholds) of DTH operations for the purposes of predicting Level A harassment using relevant impulsive source levels, and we estimate the potential continuous components of DTH (using the associated threshold) for the purposes of predicting Level B harassment using relevant continuous source levels.

For vibratory pile driving we determined a source level of 162 dB (RMS SPL) at 10m was most appropriate. The closest known measurements of sound levels for

vibratory pile installation of 24-inch steel piles are from the U.S. Navy Proxy Sound Source Study for projects in Puget Sound (U.S. Navy 2015). Based on the projects analyzed it was determined that 16- to 24-inch piles exhibited similar sound source levels. For DTH drilling we use a source level of 166.2 dB (RMS SPL) for Level B harassment zones; this is derived from Denes *et al.* (2016), where they drilled 24-inch piles near Kodiak, AK. For Level A harassment zones for DTH drilling we use the single strike source level of 154 dB SEL that was recently calculated from the same Kodiak project. To be conservative, since DTH drilling and vibratory pile driving would occur on the same day, the applicant used the higher of the vibratory and DTH source levels (162 dB ssSEL for level A and 166.2dB rms for level B harassment) for both Level A and Level B calculations and assumed all drilling/driving time in a day was at this higher level. For impact pile driving of 24-inch piles, sound measurements were used from the literature review in Appendix H of the Alaska Department of Transportation (AKDOT&PF) study (Yurk *et al.* 2015) for 24-inch piles driven in the Columbia River with a diesel impact hammer (190 dB RMS, 205 dB Peak, 175 dB SS SEL).

We assumed no more than two piles per day with DTH drilling as the duration per pile was assumed to be 6 hours. For impact pile driving activities we also assumed no more than 2 piles per day and 250 strikes per pile. In all cases we used a propagation loss coefficient of 15 logR as most appropriate for these stationary, in-shore sources.

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which may result in some degree of overestimate of Level A harassment take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources, such as pile driving and drilling in this project, NMFS User Spreadsheet predicts the distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would incur PTS. Inputs used in the User Spreadsheet, and the resulting isopleths are reported below.

NMFS User spreadsheet input scenarios for vibratory pile driving/DTH drilling and impact pile driving are shown in Table 3. These input scenarios lead to PTS isopleth distances (Level A thresholds) of anywhere from 7 to 220 meters (22 to 720 ft), depending on the marine mammal group and scenario (Table 4).

TABLE 3—NMFS USER SPREADSHEET INPUTS

User spreadsheet input	Vibratory pile driving/DTH drilling—continuous	DTH drilling—impulsive	Impact pile driving
Spreadsheet Tab Used	A.1) Vibratory pile driving.	E.1–2) Impact pile driving.	E.1) Impact pile driving.
Source Level	166.2 dB RMS	154 dB SS SEL	175 dB SS SEL.
Weighting Factor Adjustment (kHz)	2.5	2	2.
a) Number of strikes per pile	N/A	10,000	250.
a) Activity Duration (h:min) within 24-h period	12:00	N/A	N/A.
Propagation (xLogR)	15	15	15.
Distance of source level measurement (meters)	10	10	10.
Number of piles per day	2	2	2.

TABLE 4—NMFS USER SPREADSHEET OUTPUTS: LEVEL B AND LEVEL A (PTS) ISOPLETHS

Activity	Behavioral disturbance (level B) all species	PTS isopleths (meters) (level A)				
		Humpback + Minke whales	Killer whales	Harbor + Dall's porpoise	Harbor seals	Stellar sea lions
Vibratory Driving/DTH drilling—continuous.	12.1 km (7.5 miles) *.	80 m (263 ft)	7 m (23 ft)	118 m (387 ft)	48 m (158 ft)	4 m (13 ft).
DTH drilling—impulsive	N/A	137 m (447 ft)	5 m (16 ft)	163 m (532 ft)	73 m (239 ft)	6 m (17 ft).
Impact Driving	1 km (3280 ft)	184 m (605 ft)	7 m (23 feet)	220 m (720 ft)	99 m (325 ft)	8 m (25 ft).

* Lynn Canal is smaller than this, therefore extent of actual impacts will be constrained by land.

The distances to the Level B harassment threshold of 120 dBrms are 12.1 kilometers (km) (7.5 miles (mi)) for vibratory pile driving/DTH drilling and 1 km (3280 feet (ft)) for impact driving. The enclosed nature of the area restricts the propagation of noise in most directions before noise levels reduce below the Level B harassment threshold for vibratory pile driving/DTH) Therefore, the area ensonified to the Level B harassment threshold is truncated by land in most directions. The ensonified area of the vibratory/drilling Level B harassment zone is 47km^2 (18.15 mi^2). Note that thresholds for behavioral disturbance are unweighted with respect to marine mammal hearing and therefore the thresholds apply to all species.

Marine Mammal Occurrence and Take Calculation and Estimation

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations. We have density information for two species: Dall's porpoise and harbor porpoise. For the other five species we have information on presence, group size, and dive durations that we use to derive take estimates.

In this section we then describe for each species how the marine mammal occurrence and/or density information is brought together to produce a quantitative take estimate. Level A harassment takes are requested for Dall's porpoise and harbor porpoise only as they are more cryptic and could enter a Level A harassment zone undetected. For the other species, the Level A harassment zones are small and shutdown measures can be implemented prior to any individual entering the Level A harassment zones. Take estimates for all stocks are shown in Table 5.

Humpback Whale

Based on local information and Dahlheim *et al.* (2009) we estimate that up to eight individuals could be exposed to underwater noise each day. Our take estimate is then the product of the number of individuals per day times the 6 days of the project, or 48 Level B takes.

For purposes of estimating effects and ESA takes of the Mexico DPS of humpback whales, we acknowledge that Mexico DPS whales cannot be readily distinguished from non-listed humpback whales in the project area. Based on Wade *et al.* (2016) we estimate that 3 of the 48 takes will be of the Mexico DPS.

While individual humpback whales can generally be identified, due to the size of the monitoring zone it is possible this won't be the case in some instances. Further, it is possible that different monitors will sight the same whale, given the size of the monitoring zones and the distances humpback whales can move in a day. Thus it is conservatively assumed that there could be up to three interactions with each individual daily. PSOs may thus initially record more sightings than allowed takes until individuals being observed multiple time per day can be verified.

Steller Sea Lions

As discussed above Steller sea lions are typically absent in the project area from mid-July through September. On the off chance that Steller sea lions will be present during construction for this project we used an average of the three sightings discussed above from 2005 and 2013 to estimate the possible number of animals in the area. This average was 248 individuals. We assume that no more than 248 individual Steller sea lions will enter the action area on a given day of the project and calculate expected take as 248 times the 6 days of the project, or 1,488 takes. As discussed above, some of these takes will be eastern DPS Steller sea lions and some will be western DPS. We use the estimate from Hastings *et al.* (2020) that 1.4 percent of the animals in the project area are from the western DPS to allot 21 of the 1,488 Level B takes to the western DPS and 1,467 of the takes to the eastern DPS.

Harbor Seal

As discussed above, researchers estimate that they are 95 percent confident the population size of harbor seals in the area is not greater than 134 individuals. We use that estimate as the number of animals expected in the Level B harassment zone daily. Our take estimate is then the product of the number of individuals per day times the 6 days of the project, or 804 Level B takes.

We know from Klinkhart *et al.* (2008) that animals dive and resurface every 4 minutes. That translates to potentially 15 sightings per hour. We also use the estimate that they spend 50 percent of their time hauled out. The project involved 36 hours of pile driving/drilling total. Individual sightings is estimated to be 134 seals times 7.5 in-water sightings per hour times 36 hours of work, or 36,180 sightings. PSOs may thus initially record more sightings than allowed takes until individuals being observed multiple time per day can be verified.

Dall's Porpoise

Density estimates were determined for Dall's porpoises for areas in Southeast Alaska, however densities specific to the Lynn Canal/Favorite Channel area are not available. However, surveys occurred closest to the project area in 1991, 1992, and 2007. These surveys found densities (porpoises/100km^2) during summer months of 18.5, 14.3, and 17.8 (Dahlheim *et al.,* 2009). We used the average of these densities (16.9 porpoises/100 km^2) to calculate take. As noted above the ensonified area is 47 km^2. Thus estimated take is 16.9/100 km^2 times 47 km^2 times 6 days, or 48 takes.

Due to the size of the Level A harassment zone associated with drilling, and the cryptic nature of Dall's porpoises, it is possible Dall's porpoises may enter the Level A harassment zones undetected. It is conservatively assumed that up to four harbor porpoises (the mean group size from Dahlheim *et al.* 2009) may enter the Level A harassment once during the duration of the project. Thus we allot the 48 takes above to 4 Level A takes and 44 Level B takes.

Harbor Porpoise

Density was estimated for harbor porpoises in Lynn Canal by Dahlhein *et al.* (2015) to be 0.2 individuals/km^2. As noted above the ensonified area is 47 km^2. Thus estimated take is 0.2/km^2 times 47 km^2 times 6 days, or 57 takes.

Due to the size of the Level A harassment zone associated with drilling, and the stealthy nature of harbor porpoises with no visible blow and a low profile, it is possible harbor porpoises may enter the Level A harassment zone undetected. Because they are most commonly observed in pairs (Dahlheim *et al.* 2009), it is conservatively assumed that one pair of harbor porpoises may enter the Level A harassment zone every other day of pile driving. Thus we allot the 57 takes above to 6 Level A takes and 51 Level B takes.

Killer Whale

Based on the information available as discussed above, it is conservatively estimated that 2 interactions with the average group size of residents (33) and 2 interactions with the average group size of transients (5) may be occur during the 6 days of the project. Thus we expect 76 Level B takes of killer whales.

Minke Whale

There are no known occurrences of minke whales within the project area, however since their ranges extend into the project area and they have been observed in southeast Alaska (Dahlheim *et al.,* 2009), it is possible minke whales could occur near the project. It is estimated up to one minke whale could be exposed to elevated noise levels from the project. Therefore, 1 Level B take is proposed to be authorized.

TABLE 5—PROPOSED AUTHORIZED LEVEL A AND B TAKE AND PERCENT OF MMPA STOCK PROPOSED TO BE TAKEN

Species	Proposed authorized take		% of Stock
	Level B	Level A	
Humpback Whale [1]	48	0	1.4
Minke Whale	1	0	N/A
Killer Whale	76	0	2.9
Harbor Porpoise	51	6	5.9
Dall's Porpoise	44	4	N/A
Harbor Seal	804	0	8.5
Steller Sea Lion (Eastern DPS) [2]	1467	0	3.5
Steller Sea Lion (Western DPS) [2]	21	0	0.04

[1] Distribution of proposed take by ESA status is 36 Level B takes for Hawaii DPS and 12 Level B take for Mexico DPS.
[2] Total estimated take of Steller sea lions was 1488. Distribution between the stocks was calculated assuming 1.4% Western DPS and rounding to nearest whole number.

Effects of Specified Activities on Subsistence Uses of Marine Mammals

The availability of the affected marine mammal stocks or species for subsistence uses may be impacted by this activity. The subsistence uses that may be affected and the potential impacts of the activity on those uses are described below. The information from this section is analyzed to determine whether the necessary findings may be made in the Unmitigable Adverse Impact Analysis and Determination section.

Subsistence harvest of harbor seals and Steller sea lions by Alaska Natives is not prohibited by the MMPA. No records exist of subsistence harvests of whales and porpoises in Lynn Canal (Haines, 2007). The Alaska Department of Fish and Game (ADF&G) has regularly conducted surveys of harbor seal and Steller sea lion subsistence harvest in Alaska and the number of Steller sea lions taken for subsistence in this immediate area from 1992–2008, and 2012 is only two (Wolfe *et al.* 2013). Subsequent to the 2012 reporting year through 2017, an estimated one to three Steller sea lions have been taken annually outside Sitka Sound (personal communication with Lauren Sill, ADF&G, 83 FR 52394; October 17, 2018). Based upon data for harbor seal harvests, hunters in Southeast Alaska took from 523 to 719 harbor seals annually in the years 1992–2008. In 2012 an estimated 595 harbor seals were taken for subsistence uses (Wolfe *et al.* 2013). Seals were harvested across the year, with peak harvests in March, May, and October. Most recent reported data for the Juneau area indicates that in 2012, an estimated 26 harbor seal were harvested for food (Wolfe *et al.* 2013). From 2013 through 2019, Juneau area harbor seal hunting has continued, with several cultural heritage programs teaching students how to harvest, cut and store seal meat. However, there is no information on take numbers from 2013–2019 (personal communication with Lauren Sill, ADF&G).

Since there is very little sea lion hunting in the Juneau area, short term displacement of animals from the project area is anticipated to have no effect on abundance or availability of Steller sea lions to subsistence hunters. Further, due to the project timing, Steller sea lions are typically absent from the project area and it is likely none will be displaced. The Douglas Indian Association, Sealaska Heritage Institute, and the Central Council of the Tlingit and Haida Indian Tribes of Alaska (Central Council) were contacted during December 2019 to discuss this project. The Douglas Indian Association responded that they did not see any impacts that may affect their subsistence use. Chuck Smythe, with the Sealaska Heritage Institute, responded indicating that there is known harbor seal hunting in the project area. The other groups have not responded.

Construction activities at the project site would be expected to cause only short term, non-lethal disturbance of marine mammals. Construction activities are localized and temporary, mitigation measures will be implemented to minimize disturbance of marine mammals in the action area, and, the project will not result in significant changes to availability of subsistence resources. Impacts on the abundance or availability of either species to subsistence hunters in the region are thus not anticipated.

Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

The following mitigation measures are in the IHA:

- *Schedule:* Pile driving or removal would occur during daylight hours. If poor environmental conditions restrict visibility (*e.g.,* from excessive wind or

fog, high Beaufort state), pile installation would be delayed. No pile driving would occur from March 1 through May 31 to avoid peak marine mammal abundance periods and critical foraging periods;

• *Pile Driving Delay/Shut-Down:* For use of in-water heavy machinery/vessel (*e.g.,* dredge), GCHS will implement a minimum shutdown zone of 10 m radius around the pile/vessel. For vessels, GCHS must cease operations and reduce vessel speed to the minimum required to maintain steerage and safe working conditions. In addition, if an animal comes within the shutdown zone (see Table 6) of a pile being driven or removed, GCHS would shut down. The shutdown zone would only be reopened when a marine mammal has not been observed within the shutdown zone for a 15 minutes have passed without subsequent detections of small cetaceans and pinnipeds; or 30 minutes have passed without subsequent detections of large cetaceans. If pile driving is stopped, pile installation would not commence if pile any marine mammals are observed anywhere within the Level A harassment zone. Pile driving activities would only be conducted during daylight hours when it is possible to visually monitor for marine mammals. If a species for which authorization has not been granted, or if a species for which authorization has been granted but the authorized takes are met, GCHS would delay or shut-down pile driving if the marine mammal approaches or is observed within the Level A and/or B harassment zones;

• *Soft-start:* For all impact pile driving, a ''soft start'' technique will be used at the beginning of each pile installation day, or if pile driving has ceased for more than 30 minutes, to allow any marine mammal that may be in the immediate area to leave before hammering at full energy. The soft start requires GCHS to provide an initial set of three strikes from the impact hammer at reduced energy, followed by a 30 second waiting period, then two subsequent 3-strike sets. If any marine mammal is sighted within the Level A shutdown zone prior to pile-driving, or during the soft start, GCHS will delay pile-driving until the animal is confirmed to have moved outside and is on a path away from the Level A harassment zone or if 15 minutes have passed without subsequent detections of small cetaceans and pinnipeds; or 30 minutes have passed without subsequent detections of large cetaceans; and

• *Other best management practices:* GCHS will drive all piles with a vibratory hammer to the maximum extent possible (*i.e.,* until a desired depth is achieved or to refusal) prior to using an impact hammer and will use DTH drilling prior to using an impact hammer. GCHS will also use the minimum hammer energy needed to safely install the piles.

Based on our evaluation of the applicant's proposed measures, NMFS has determined that the mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses.

TABLE 6—SHUTDOWN ZONES FOR EACH ACTIVITY TYPE AND STOCK

Source	Shutdown zone—permitted species					Level B harassment zone
	Low-frequency cetaceans	Mid-frequency cetaceans	High-frequency cetaceans	Phocids	Otariids	All species
Vibratory	80 m (265 ft)	10 m (35 ft)	120 m (395 ft)	50 m (165 ft)	10 m (35 ft)	12.1 km (7.5 miles).
DTH drilling	140 m (460 ft)	10 m (35 ft)	165 m (213 ft)	75 m (246 ft)	10 m (35 ft)	12.1 km (7.5 miles).
Impact Pile Driving	185 m (605 ft)	10 m (35 ft)	220 m (720 ft)	100 m (325 ft)	10 m (35 ft)	1000 m (3280 ft).

Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

• Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);

• Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);

• Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;

• How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;

• Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and

• Mitigation and monitoring effectiveness.

Visual Monitoring

Monitoring would be conducted 30 minutes before, during, and 30 minutes after pile driving activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in

concert with distance from piles being driven or removed. Pile driving activities include the time to install a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

A primary PSO would be placed at the project site where pile driving would occur. The primary purpose of this observer is to monitor and implement the Level A shutdown zones. Two additional observers would focus on monitoring large parts of the Level B harassment zone as well as visible parts of the Level A shutdown and harassment zones. The locations are shown in Figure 2 of the monitoring plan. Since not all of the Level B harassment zone will be observable by PSOs, they will calculate take for the project by extrapolating the observable area for each stock to the total size of the Level B harassment zone. PSOs would scan the waters using binoculars, and/or spotting scopes, and would use a handheld GPS or range-finder device to verify the distance to each sighting from the project site. All PSOs would be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. The following measures also apply to visual monitoring:

(1) Monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Qualified observers are trained biologists, with the following minimum qualifications;

(a) Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;

(b) Advanced education in biological science or related field (undergraduate degree or higher required);

(c) Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);

(d) Experience or training in the field identification of marine mammals, including the identification of behaviors;

(e) Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

(f) Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and

(g) Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary; and

(2) GCHS shall submit observer Curriculum Vitaes for approval by NMFS.

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of pile driving activities, or 60 days prior to a requested date of issuance of any future IHAs for projects at the same location, whichever comes first. It will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated marine mammal observation data sheets. Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including how many and what type of piles were driven or removed and by what method (*i.e.,* impact or vibratory);
- Weather parameters and water conditions during each monitoring period (*e.g.,* wind speed, percent cover, visibility, sea state);
- The number of marine mammals observed, by species, relative to the pile location and if pile driving or removal was occurring at time of sighting;
- Age and sex class, if possible, of all marine mammals observed;
- PSO locations during marine mammal monitoring;
- Distances and bearings of each marine mammal observed to the pile being driven or removed for each sighting (if pile driving or removal was occurring at time of sighting);
- Description of any marine mammal behavior patterns during obsevation, including direction of travel and estimated time spent within the Level A and Level B harassment zones while the source was active;
- Number of individuals of each species (differentiated by month as appropriate) detected within the monitoring zone, and estimates of number of marine mammals taken, by species (a correction factor may be applied to total take numbers, as appropriate;
- Detailed information about any implementation of any mitigation triggered (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting behavior of the animal, if any;
- Description of attempts to distinguish between the number of individual animals taken and the number of incidences of take, such as ability to track groups or individuals;
- An extrapolation of the estimated takes by Level B harassment based on the number of observed exposures within the Level B harassment zone and the percentage of the Level B harassment zone that was not visible; and
- Submit all PSO datasheets and/or raw sighting data (in a separate file from the Final Report referenced immediately above).

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, the IHA-holder shall report the incident to the Office of Protected Resources (OPR) (301–427–8401), NMFS and to the Alaska Regional Stranding Coordinator as soon as feasible. If the death or injury was clearly caused by the specified activity, the IHA-holder must immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. The IHA-holder must not resume their activities until notified by NMFS. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analyses applies to all the species listed in Table 5, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is little information about the nature or severity of the impacts, or the size, status, or structure of any of these species or stocks that would lead to a different analysis for this activity. Pile driving and drilling activities have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level A harassment and Level B harassment from underwater sounds generated from pile driving and DTH drilling. Potential takes could occur if individuals of these species are present in the ensonified zone when these activities are underway.

The takes from Level A and Level B harassment would be due to potential behavioral disturbance, Temporary Threshold Shift (TTS), and PTS. No mortality is anticipated given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. Level A harassment is only authorized for Dall's porpoise and harbor porpoise. The potential for harassment is minimized through the construction method and the implementation of the planned mitigation measures (see Mitigation section).

Behavioral responses of marine mammals to pile driving at the project site, if any, are expected to be mild and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities (as noted during modification to the Kodiak Ferry Dock) or could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the short duration of noise-generating activities per day and that pile driving would occur on no more than 4 days, any harassment would be temporary. In addition, GCHS would not conduct pile driving during the spring eulachon and herring runs, when marine mammals are in greatest abundance and engaging in concentrated foraging behavior. There are no other areas or times of known biological importance for any of the affected species.

In addition, although some affected humpback whales and Steller sea lions may be from a DPS that is listed under the ESA, it is unlikely that minor noise effects in a small, localized area of habitat would have any effect on the stocks' ability to recover. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities will have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality is anticipated or authorized;
- Authorized Level A harassment would be very small amounts and of low degree for two cryptic species;
- GCHS would avoid pile driving during peak periods of marine mammal abundance and foraging (*i.e.,* March 1 through May 31 eulachon and herring runs);
- GCHS would implement mitigation measures such as vibratory driving piles to the maximum extent practicable, soft-starts, and shut downs; and
- Monitoring reports from similar work in Alaska have documented little to no effect on individuals of the same species impacted by the specified activities.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The amount of take NMFS proposes to authorize is less than one-third of any stock's best population estimate (and in fact, no more than 10 percent for any stock). These are all likely conservative estimates because we assume all takes are of different individual animals which is likely not the case, especially for harbor seals and Steller sea lions, which have the largest take. The Alaska stock of Dall's porpoise has no official NMFS abundance estimate as the most recent estimate is greater than eight years old. Nevertheless, the most recent estimate was 83,400 animals and it is highly unlikely this number has drastically declined. Therefore, the 48 authorized takes of this stock clearly represent small numbers of this stock. The Alaska stock of minke whale has no stock-wide abundance estimate. The stock ranges from the Bering and Chukchi seas south through the Gulf of Alaska. Surveys in portions of the range have estimated abundances of 2,020 on the eastern Bering Sea shelf and 1,233 from the Kenai Fjords in the Gulf of Alaska to the central Aleutian Islands. Thus there appears to be thousands of

animals at least in the stock and clearly the 1 authorized takes of this stock represent small numbers of this stock.

Based on the analysis contained herein of the proposed activity (including the mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an ''unmitigable adverse impact'' on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

As discussed above in the subsistence uses section, subsistence harvest of harbor seals and other marine mammals is rare in the area and local subsistence users have not expressed concern about this project. All project activities will take place within the Favorite Channel area where subsistence activities do not generally occur. The project also will not have an adverse impact on the availability of marine mammals for subsistence use at locations farther away, where these construction activities are not expected to take place. Some minor, short-term harassment of the harbor seals and Steller sea lions could occur, but any effects on subsistence harvest activities in the region will be minimal, and not have an adverse impact.

Based on the effects and location of the specified activity, and the mitigation and monitoring measures, NMFS has determined that there will not be an unmitigable adverse impact on subsistence uses from GCHS's planned activities.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with the Alaska Region Protected Resources Division Office, whenever we propose to authorize take for endangered or threatened species.

NMFS is proposing to authorize take of Western DPS Steller sea lion (*Eumetopias jubatus*) and Mexico DPS of humpback whales (*Megaptera novaeangliae*), which are listed under the ESA. The NMFS Alaska Regional Office Protected Resources Division issued a Biological Opinion on June 25, 2020 under section 7 of the ESA, on the issuance of an IHA to GCHS under section 101(a)(5)(D) of the MMPA by the NMFS Permits and Conservation Division. The Biological Opinion concluded that the proposed action is not likely to jeopardize the continued existence of the above species, and is not likely to destroy or adversely modify western DPS Steller sea lion critical habitat.

Authorization

NMFS has issued an IHA to GCHS for the potential harassment of small numbers of seven marine mammal species incidental to conducting the Sentinel Island Moorage Float project near Juneau, Alaska between July 15, 2020 and September 20, 2020, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: July 9, 2020.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–15198 Filed 7–14–20; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 1:00 p.m. EDT, Wednesday, July 22, 2020 and 10:00 a.m. EDT, Thursday, July 23, 2020.

PLACE: Conference call.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') will hold these meetings to consider the matters described herein.

To be considered at the July 22, 2020 meeting:

- *Final Rule*: Capital Requirements of Swap Dealers and Major Swap Participants; and
- *Proposed Rules*: Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants.

To be considered at the July 23, 2020 meeting:

- *Amendment Order*: Exempting Certain Multilateral Trading Facilities and Organised Trading Facilities Authorized Within the European Union from the Requirement to Register with the Commodity Futures Trading Commission as Swap Execution Facilities; and
- *Final Rule*: Cross-Border Application of the Registration Thresholds and Certain Requirements Applicable to Swap Dealers and Major Swap Participants.

The agenda for each meeting will be available to the public and posted on the Commission's website at *https://www.cftc.gov.* Instructions for public access to the live audio feed of the meetings will also be posted on the Commission's website. In the event that the time, date, or place of these meetings change, an announcement of the change, along with the new time, date, or place of the meeting, will be posted on the Commission's website.

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, Secretary of the Commission, 202–418–5964.

Authority: 5 U.S.C. 552b.

Dated: July 13, 2020.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2020–15429 Filed 7–13–20; 4:15 pm]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2020–HQ–0014]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: Rescindment of six System of Records notices (SORNs).

SUMMARY: The Department of the Army is rescinding six Human Resource (HR) SORNs. The notices consist of the: Individual Ready, Standby, and Retired Reserve Personnel Information System, A0600–8 AHRC; Standard Installation/Division Personnel System, A0600–8–23; Integrated Personnel and Pay System—Army Records, A0600–8a PEO EIS; Classification and Reclassification of Soldiers, A0614–200 AHRC; Officer Personnel Management Information System, A0680–31a; and Enlisted Personnel Management Information System, A0680–31b. These notices are incorporated into the Privacy Act SORN, ''A0600–8–104 AHRC, Army Personnel Systems (APS).''

DATES: This System of Records rescindment is effective upon publication. These systems of records were rendered obsolete with the publication of Army Personnel Systems (APS), A0600–8–104 AHRC in the **Federal Register** on July 18, 2018.

FOR FURTHER INFORMATION CONTACT: Mr. Myron Wong, Department of the Army, U.S. Army Records Management and Declassification Agency, ATTENTION: Army Privacy and Civil Liberties Office, 9301 Chapek Road (Building 1458), Fort Belvoir, VA 22060–5605, or by calling 571–515–0243.

SUPPLEMENTARY INFORMATION: On July 18, 2018, the Department of the Army published a modified Privacy Act SORN titled, ''A0600–8–104 AHRC, Army Personnel Systems (APS)'' (84 FR 34373). The modification incorporated six HR SORNs: A0600–8 AHRC, A0600–8–23, A0600–8a PEO EIS, A0614–200 AHRC, A0680–31a, and A0680–31b.

The DoD notices for Systems of Records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Defense Privacy, Civil Liberties, and Transparency Division website at *https://dpcld.defense.gov.*

The proposed system reports, as required by the Privacy Act, as amended, were submitted on June 15, 2020, to the House Committee on Oversight and Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to Section 6 of OMB Circular No. A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,'' revised December 23, 2016 (December 23, 2016, 81 FR 94424).

SYSTEM NAMES AND NUMBERS:

Individual Ready, Standby, and Retired Reserve Personnel Information System, A0600–8 AHRC.

HISTORY:

January 6, 2004, 69 FR 796. Standard Installation/Division Personnel System, A0600–8–23.

HISTORY:

May 3, 2013, 78 FR 25974. Integrated Personnel and Pay System—Army Records, A0600–8a PEO EIS.

HISTORY:

June 09, 2011, 76 FR 33728. Classification and Reclassification of Soldiers, A0614–200 AHRC.

HISTORY:

May 3, 2013, 78 FR 25974. Officer Personnel Management Information System, A0680–31a.

HISTORY:

August 18, 2004, 69 FR 51271. Enlisted Personnel Management Information System, A0680–31b.

HISTORY:

January 6, 2004, 69 FR 790.

Dated: July 10, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–15268 Filed 7–14–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Number: PR20–70–000.

Applicants: Regency Intrastate Gas LP.

Description: Tariff filing per 284.123(b)(2)+(: Regency Intrastate Gas LP Petition for Rate Approval and Revised SOC to be effective 6/2/2020.

Filed Date: 7/2/2020.

Accession Number: 202007025067.

Comments/Protests Due: 5 p.m. ET 7/23/2020.

Docket Numbers: RP20–1006–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: Section 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Marathon 51754 to ConocoPhillips 52929) to be effective 7/1/2020.

Filed Date: 7/2/20.

Accession Number: 20200702–5069.

Comments Due: 5 p.m. ET 7/14/20.

Docket Numbers: RP20–1007–000.

Applicants: Dominion Energy Cove Point LNG, LP.

Description: Compliance filing DECP—2020 Penalty Revenue Distribution.

Filed Date: 7/2/20.

Accession Number: 20200702–5098.

Comments Due: 5 p.m. ET 7/14/20.

Docket Numbers: RP20–1008–000.

Applicants: Rover Pipeline LLC.

Description: Section 4(d) Rate Filing: Reservation Charge Credit GTC 25 Clarification to be effective 8/2/2020.

Filed Date: 7/2/20.

Accession Number: 20200702–5155.

Comments Due: 5 p.m. ET 7/14/20.

Docket Numbers: RP20–1009–000.

Applicants: Dominion Energy Transmission, Inc.

Description: Compliance filing DETI—2020 Overrun and Penalty Revenue Distribution.

Filed Date: 7/2/20.

Accession Number: 20200702–5163.

Comments Due: 5 p.m. ET 7/14/20.

Docket Numbers: RP20–1010–000.

Applicants: West Texas Gas, Inc.

Description: Annual Purchased Gas Cost Reconciliation Report of West Texas Gas, Inc. under RP20–1010.

Filed Date: 7/1/20.

Accession Number: 20200701–5530.

Comments Due: 5 p.m. ET 7/13/20.

Docket Numbers: RP20–1011–000.

Applicants: Viking Gas Transmission Company.

Description: Section 4(d) Rate Filing: Compliance Filing to Implement Revised Tariff Records to be effective 8/1/2020.

Filed Date: 7/2/20.

Accession Number: 20200702–5228.

Comments Due: 5 p.m. ET 7/14/20.

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 date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 7, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–15042 Filed 7–14–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP20–50–000; CP20–51–000]

Tennessee Gas Pipeline Company, LLC, Southern Natural Gas Company, LLC; Notice of Revised Schedule for Environmental Review of the Evangeline Pass Expansion Project

This notice identifies the Federal Energy Regulatory Commission staff's revised schedule for the completion of the environmental assessment (EA) for Tennessee Gas Pipeline Company LLC's (Tennessee) and Southern Natural Gas Company LLC's (SNG) Evangeline Pass Expansion Project. The first notice of schedule, issued on April 3, 2020, identified July 27, 2020 as the EA issuance date. On April 13, 2020 and June 12, 2020, FERC staff requested additional environmental information to assist in its EA analysis regarding pile driving and associated noise and vibration impacts on aquatic species, including essential fish habitat and threatened and endangered species; floodplain development; and horizontal directional drilling. Tennessee filed a portion of the requested information on June 30, 2020 and stated that the additional information would be filed on July 14, 2020. To provide appropriate time to review and complete the analysis of the necessary supplemental information, Commission staff has revised the schedule for issuance of the EA, as described below.

Schedule for Environmental Review

Issuance of EA—August 24, 2020

90-day Federal Authorization Decision Deadline—November 23, 2020

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the project's progress.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Additional information about the project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the eLibrary link, enter the ''Docket Number'' excluding the last three digits (*i.e.,* CP20–50 or CP20–51), select a date range, and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: July 9, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–15266 Filed 7–14–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–490–000]

Columbia Gulf Transmission, LLC; Notice of Application

Take notice that on June 30, 2020, Columbia Gulf Transmission, LLC, 700 Louisiana Street, Suite 700, Houston, Texas 77002, filed an application pursuant to section 7(c) and 7(b) of the Natural Gas Act (NGA) and, Part 157 of the Commission's regulations for authority to implement its Mainline 300 Replacement Project (Replacement Project). The Replacement Project consists of the abandonment and replacement of two segments of the 36-inch-diameter Mainline 300 totaling approximately 775 feet. The Replacement Project is located in (Menifee and Montgomery Counties, Kentucky), all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review on the Commission's website 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, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TYY, (202) 502–8659. 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.

Any questions concerning this application may be directed to Dave Hammel, Columbia Gulf Transmission, LLC, 700 Louisiana Street, Suite 700, Houston, TX 77002–2700, 832.320.5861, *dave_hammel@tcenergy.com*

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18

CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list and will be notified of any meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

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://wwwferc.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.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16–4–001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any new NGA section 3 or section 7 proceeding.[1] Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to ''show good cause why the time limitation should be waived,'' and should provide justification by reference to factors set forth in Rule 214(d)(1) of the Commission's Rules and Regulations.[2]

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* 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.

Comment Date: 5:00 p.m. Eastern Time on July 30, 2020.

Dated: July 9, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–15272 Filed 7–14–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP20–1015–000.

Applicants: Rockies Express Pipeline LLC.

Description: Section 4(d) Rate Filing: REX 2020–07–07 Negotiated Rate Agreement Amendment to be effective 7/10/2020.

Filed Date: 7/7/20.

Accession Number: 20200707–5059.

Comments Due: 5 p.m. ET 7/20/20.

Docket Numbers: RP20–1016–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Compliance filing Rate Schedule S–2 Flow Through Refund Texas Eastern Rate Case.

Filed Date: 7/7/20.

Accession Number: 20200707–5094.

Comments Due: 5 p.m. ET 7/20/20.

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 date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 9, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–15273 Filed 7–14–20; 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: ER10–1626–013.

Applicants: Tenaska Virginia Partners, L.P.

Description: Notification of Change in Status of Tenaska Virginia Partners, L.P.

Filed Date: 7/9/20.

Accession Number: 20200709–5146.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER17–1609–004.

Applicants: Carroll County Energy LLC.

Description: Notification of Change in Status of Carroll County Energy LLC.

Filed Date: 7/9/20.

Accession Number: 20200709–5145.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–1718–001.

Applicants: New York Independent System Operator, Inc.

Description: Tariff Amendment: Response to deficiency letter re: Part A enhancements under BSM rules to be effective 9/8/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5135.

[1] *Tennessee Gas Pipeline Company, L.L.C.,* 162 FERC ¶ 61,167 at ¶ 50 (2018).

[2] 18 CFR 385.214(d)(1).

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–1866–001.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Amendment to ISA, SA No. 5660 and ICSA, SA No. 5661; Queue No. AC1–042 (amend) to be effective 4/20/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5139.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–1917–001.

Applicants: EF Oxnard LLC.

Description: Tariff Amendment: Deficiency filing under docket ER20–1917 to be effective 6/1/2020.

Filed Date: 7/8/20.

Accession Number: 20200708–5146.

Comments Due: 5 p.m. ET 7/29/20.

Docket Numbers: ER20–2350–000.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Notice of Cancellation of ICSA, SA No. 1858; Queue No. P06 to be effective N/A.

Filed Date: 7/8/20.

Accession Number: 20200708–5135.

Comments Due: 5 p.m. ET 7/29/20.

Docket Numbers: ER20–2351–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Section 205(d) Rate Filing: Amendment to Service Agreement No. 870 to be effective 7/2/2020.

Filed Date: 7/8/20.

Accession Number: 20200708–5140.

Comments Due: 5 p.m. ET 7/29/20.

Docket Numbers: ER20–2352–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2020–07–09_SA 1972 GRE–OTP 4th Rev GIA (G645 G788) to be effective 7/6/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5002.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2353–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2020–07–09_SA 3510 OTP–GRE FSA (G788) to be effective 8/1/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5005.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2354–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2020–07–09_SA 3525 MDU–NSP FSA Twin Brooks-Ellendale (J436 and J437) to be effective 7/1/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5020.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2355–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2020–07–09_SA 3056 MDU–NSP MPFCA 1st Rev Ellendale (J436 and J437) to be effective 7/6/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5017.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2356–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of ISA, SA No. 2790 to be effective 9/17/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5066.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2357–000.

Applicants: Alabama Power Company.

Description: Section 205(d) Rate Filing: Anniston Solar LGIA Filing to be effective 6/26/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5067.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2358–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of ISA, SA No. 4113; Queue No. T182 to be effective 9/20/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5074.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2359–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Original ISA, SA No. 5697; Queue No. AF1–179 to be effective 6/11/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5116.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2360–000.

Applicants: California Independent System Operator Corporation.

Description: Section 205(d) Rate Filing: 2020–07–09 Commitment Costs and Default Energy Bid Enhancements to be effective 12/31/9998.

Filed Date: 7/9/20.

Accession Number: 20200709–5132.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2361–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Original ISA, Service Agreement No. 5683; Queue No. AF1–199 to be effective 6/11/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5141.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2362–000.

Applicants: The Empire District Electric Company.

Description: Compliance filing: Compliance Filing—Amendment to Market-Based Rate Tariff to be effective 5/1/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5149.

Comments Due: 5 p.m. ET 7/30/20.

Docket Numbers: ER20–2363–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Original WMPA SA No. 5671; Queue No. AF1–058 to be effective 6/11/2020.

Filed Date: 7/9/20.

Accession Number: 20200709–5166.

Comments Due: 5 p.m. ET 7/30/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 9, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–15274 Filed 7–14–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12726–002]

Warm Springs Hydro, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the application for license for the Rock Creek Hydroelectric Project (project)

and has prepared an Environmental Assessment (EA). The project is located on Rock Creek near the City of Haines in Baker County, Oregon, and occupies federal lands administered by the Forest Service.

In the EA, Commission staff analyzes the potential environmental effects of the project and concludes that issuing a license for the project, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The Commission provides all interested persons an opportunity to view and/or print the EA 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 Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659. You may also register online at *https://ferconline.ferc.gov/eSubscription.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 45 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.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. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. The first page of any filing should include docket number P–12726–002.

For further information, please contact Kelly Wolcott at (202) 502–6480 or at *kelly.wolcott@ferc.gov.*

Dated: July 9, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–15260 Filed 7–14–20; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011284–081.

Agreement Name: Ocean Carrier Equipment Management Association.

Parties: Maersk A/S and Hamburg-Sud (acting as a single party); CMA CGM S.A., APL Co. Pte Ltd., and American President Lines, Ltd., (acting as a single party); COSCO SHIPPING Lines Co., Ltd. and Orient Overseas Container Line Limited (acting as a single party); Evergreen Line Joint Service Agreement; Ocean Network Express Pte. Ltd.; Hapag-Lloyd AG and Hapag-Lloyd USA LLC (acting as a single party); HMM Co., Ltd.; Zim Integrated Shipping Services; MSC Mediterranean Shipping Company S.A.; and Wan Hai Lines Ltd.

Filing Party: Jeffrey Lawrence and Don Kassilke; Cozen O'Connor.

Synopsis: The amendment changes to the name of Hyundai Merchant Marine Co., Ltd. and updates the address for same.

Proposed Effective Date: 7/6/2020.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1560.

Dated: July 10, 2020.

JoAnne O'Bryant,

Program Analyst.

[FR Doc. 2020–15291 Filed 7–14–20; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission (FTC).

ACTION: Notice and request for comment.

SUMMARY: The FTC requests that the Office of Management and Budget (OMB) extend for three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements contained in the Fuel Rating Rule (the Rule). The current clearance expires on July 31, 2020.

DATES: Comments must be received by August 14, 2020.

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. The *reginfo.gov* web link is a United States Government website produced by OMB and the General Services Administration (GSA). Under PRA requirements, OMB's Office of Information and Regulatory Affairs (OIRA) reviews Federal information collections.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome, Attorney, Division of Enforcement, Federal Trade Commission, Room CC–9528, 600 Pennsylvania Avenue NW, Washington, DC 20580, (202) 326–2889.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the FTC has submitted to the Office of Management and Budget (''OMB'') this request for extension of the previously approved collection of information discussed below.

Title: Fuel Rating Rule (the Rule), 16 CFR part 306.

OMB Control Number: 3084–0068.

Type of Review: Extension of a currently approved collection.

Likely Respondents:

(a) *Recordkeeping:* Refiners, Producers, Importers, Distributors, and Retailers of the Covered Fuel Types.

(b) *Disclosure:* Retailers of the Covered Fuel Types.

Estimated Annual Burden Hours: 32,907 (derived from 13,417 recordkeeping hours added to 19,490 disclosure hours).

Estimated Annual Labor Costs: $389,646.

Estimated Annual Capital or Other Non-labor Costs: $77,960.

Abstract: The Fuel Rating Rule establishes standard procedures for determining, certifying, and disclosing the octane rating of automotive gasoline and the automotive fuel rating of alternative liquid automotive fuels, as required by the Petroleum Marketing Practices Act. 15 U.S.C. 2822(a)–(c). The Rule also requires refiners, producers, importers, distributors, and retailers to retain records showing how the ratings were determined, including delivery tickets or letters of certification.

Request for Comment

On May 4, 2020, the FTC sought public comment on the information collection requirements associated with the Rule. 85 FR 26470. No germane comments were received.[1] Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential'' —as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2020–15226 Filed 7–14–20; 8:45 am]

BILLING CODE 6750–01–P

[1] The Commission received four non-germane comments.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Disparities and Barriers for Pediatric Cancer Survivorship Care

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Disparities and Barriers for Pediatric Cancer Survivorship Care,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before 30 days after the date of publication of this Notice.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Disparities and Barriers for Pediatric Cancer Survivorship Care. AHRQ is conducting this systematic review pursuant to Section 903 of the Public Health Service Act, 42 U.S.C. 299a–1.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Disparities and Barriers for Pediatric Cancer Survivorship Care,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/pediatric-cancer-survivorship/protocol.*

This is to notify the public that the EPC Program would find the following information on *Disparities and Barriers for Pediatric Cancer Survivorship Care* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://*

www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Guiding Questions (GQs)

The brief will be facilitated by guiding questions, documenting research and Key Informant input.

GQ1. What are the disparities in survivorship care for pediatric cancer survivors?

GQ2. What are the barriers to survivorship care for pediatric cancer survivors who experience disparities?

GQ3. What are proposed strategies for addressing those barriers?

GQ4. What published and unpublished studies have assessed these strategies?

GQ5. What are future directions for research in addressing barriers to survivorship care for pediatric cancer survivors?

PICOTSS (populations, interventions, comparators, outcomes, timing, settings, study designs) PICOTSS	Inclusion	Exclusion
Population	All GQs: • Childhood cancer survivors (CCS) of all ages. We will accept the authors' definition of CCS. Mixed samples will be included where studies include at least 50% CCS or report a subgroup analysis. In studies not self-identifying as CCS research, we will apply the following criteria: Diagnosed before age 21, received primary acute treatment for cancer, currently in remission, eligible to receive survivorship care services, care plans, and/or models of follow-up care.	All GQs: • Studies that predominantly include other populations than CCS, that include patients diagnosed predominantly after the age of 20, that had other conditions than cancer, or that are currently undergoing treatment for cancer.
Independent variables and interventions	GQ1: • Survivorship care. We will include studies addressing healthcare approaches aimed at the health and wellbeing of cancer survivors. GQ2: • Barriers and facilitators of survivorship care for CCS. GQ3, GQ4, GQ5: • Strategies to address barriers to survivorship care and to reduce care disparities. We will include care initiatives, structured care programs, care plan, care models, and healthcare interventions aiming to address barriers or disparities. Strategies may target CCS (*e.g.,* providing patient information), healthcare providers (*e.g.,* initiating training), or healthcare systems (*e.g.,* implementing health information technologies such as telemedicine).	All GQs: • Studies without reference to survivorship care and studies not addressing care disparities, barriers to care, or strategies outside of healthcare.
Comparators	GQ1, GQ2: • We will accept the authors' choice of a participant characteristic comparator. Studies may compare subgroups to the general population of CCS or compare multiple participant subgroups defined by participant characteristics (*e.g.,* race/ethnicity, socioeconomic status, gender, rural residence, educational attainment or patient or their parents, other disparate population). GQ3: • Strategies do not need to document alternative care models in detail as long as the difference of the proposed survivorship care strategy to usual care is described. GQ4, GQ5: • Studies comparing participant subgroups as defined in GQ1 and GQ2 and studies comparing to other care strategies (no intervention, waitlist, usual care, other active strategies aiming to address barriers or disparities).	All GQs: • Studies not addressing patient characteristics or intervention characteristics.
Outcomes	GQ1, GQ2: • Disparities and barriers (causes of disparity) in: ○ Any patient outcomes related to utilization of survivorship care services, care plans, or models of care. ○ Intermediate health outcomes and adverse events (short-term). ○ Mortality (long-term, not related to cancer). ○ Late effects and morbidity (including psychosocial). ○ Quality of life and wellbeing and satisfaction with care. ○ Cost and resource utilization.	All GQs: • Studies that do not relate to disparities or barriers to survivorship care for pediatric survivors.

PICOTSS (populations, interventions, comparators, outcomes, timing, settings, study designs) PICOTSS	Inclusion	Exclusion
	GQ3: • Strategies will be documented regardless of any information on outcome effects, but strategies need to aim to prevent, reduce, or mitigate disparities and barriers to survivorship care. GQ4: • Changes (reduction) in disparities between comparison groups for outcomes listed in GQ1 and GQ2. GQ5: • Ongoing and upcoming studies need to indicate that the study will report on outcomes eligible for GQ1, GQ2, or GQ4.	
Timing	All GQs: • No timing restriction apply. Studies may address CCS who recently or long in the past experienced pediatric cancer and are now in remission.	All GQs: • No exclusions apply.
Setting(s)	All GQs: • All care settings applicable to US settings will be eligible, including primary, secondary, and tertiary care; inpatient and outpatient care; pediatric and adult care context.	All GQs: • Studies in resource-limited settings such as developing countries will be reviewed for comparability with US settings.
Study design and other limiters	All GQs: • English-language publications. GQ1, GQ2, GQ4, GQ5: • Primary studies reporting empirical data (including both quantitative and qualitative data). GQ1, GQ2: • Studies may either report on distinct subgroups, *e.g.,* dividing the sample by geographic characteristic and reporting data separately for rural and for urban participants or studies may report associations with participant characteristics, *e.g.,* reporting correlations with a factor of interest such as gender differences. GQ3: • Strategies have to have been empirically tested in a research study reporting on the outcomes of interest or have been suggested by an authoritative source such as a clinical practice guideline or relevant professional organization. GQ 4: • Studies with concurrent (*e.g.,* randomized controlled trial) or historic comparator (*e.g.,* organizational pre-post studies). Studies with results published in clinicaltrials.gov will be included regardless of whether a journal publication is available. GQ5: • Ongoing and upcoming studies have to have a published protocol or are registered in a research registry.	All GQs: • Evaluations reported only in abbreviated format (*e.g.,* in a conference abstract) with the exception of trial records. • Studies exclusively reported in non-English publications. • Systematic reviews will be retained for reference mining but are not eligible for inclusion.

Dated: July 9, 2020.

Virginia Mackay-Smith,

Associate Director.

[FR Doc. 2020–15190 Filed 7–14–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Title VI Program Performance Report (OMB 0985–0007)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This notice solicits comments on the Proposed Revised Collection and solicits comments on the information collection requirements related to the extension of the Title VI Program Performance Report.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by September 14, 2020.

ADDRESSES: Submit electronic comments on the collection of information to Leslie Green *Leslie.Green@acl.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Leslie Green, Administration for Community Living, *leslie.green@acl.hhs.gov,* 202–868–9384.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. A Collection of information includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(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.

ACL is responsible for administering the Title VI Program Performance Report. The purpose of this data collection is to fulfill the annual programmatic reporting required by the Title VI Part A/B and C grants to American Indians, Alaskan Native and Native Hawaiian Programs to provide nutrition, supportive services and caregiver services to elders and their caregivers.

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: There are 282 respondents taking 3.49 hours each to complete the response.

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Title VI PPR	282	1	3.49	984
Total				984

Dated: July 8, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–15278 Filed 7–14–20; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2223]

Clinical Investigations for Prostate Tissue Ablation Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance entitled ''Clinical Investigations for Prostate Tissue Ablation Devices.'' This guidance provides recommendations for clinical investigations for high intensity ultrasound systems for prostate tissue ablation and new types of prostatic tissue ablation devices.

DATES: The announcement of the guidance is published in the **Federal Register** on July 15, 2020.

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–2223 for ''Clinical Investigations for Prostate Tissue Ablation Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9

a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Clinical Investigations for Prostate Tissue Ablation Devices'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: John Baxley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2626, Silver Spring, MD 20993–0002, 301–796–6549.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides draft recommendations for: (1) Complying with the clinical testing special control under 21 CFR 876.4340(b)(8) for premarket notifications (510(k)s) for high intensity ultrasound systems for prostate tissue ablation and (2) collecting clinical data to support marketing submissions for new types of prostatic tissue ablation devices. High intensity ultrasound systems for prostate tissue ablation transmit high intensity therapeutic ultrasound energy into the prostate to thermally ablate a defined, targeted volume of tissue. Other prostate ablation devices achieve the same clinical effect of ablating targeted tissue volumes using different sources of energy.

The scope of this guidance is limited to the clinical investigations of prostate tissue ablation systems to support marketing authorization for a general indication for ablation of prostatic tissue. This guidance does not address the clinical investigations of devices that are intended to treat specific prostatic diseases (*e.g.,* prostate cancer or benign prostatic hyperplasia). Additionally, this document does not address recommendations for non-clinical testing of prostate tissue ablation systems.

A notice of availability for the draft guidance appeared in the **Federal Register** of June 26, 2019 (84 FR 30125). FDA considered comments received and revised the guidance as appropriate in response to the comments, including minor edits to clarify and better explain FDA's recommendations for the clinical study design. 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 clinical investigations for prostate tissue ablation devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Clinical Investigations for Prostate Tissue Ablation Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16011 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910–0755
56	Institutional Review Boards	0910–0130

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15263 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0567]

Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes the Food and Drug Administration (FDA or Agency) to award priority review vouchers (PRVs) to tropical disease product applicants when the applications meet certain criteria. The FD&C Act lists the diseases that are considered tropical diseases for purposes of obtaining PRVs and provides for Agency expansion of that list to include other diseases that satisfy the definition of ''tropical diseases'' as set forth in the FD&C Act. The Agency has determined that brucellosis satisfies this definition and is therefore adding it to the list of designated tropical diseases whose product applications may result in the award of PRVs. Sponsors submitting certain drug or biological product applications for the prevention or treatment of brucellosis may be eligible to receive a PRV if such applications are approved by FDA.

DATES: This order is issued on July 15, 2020.

ADDRESSES: Submit electronic comments on additional diseases suggested for designation to *https://www.regulations.gov.* Submit written comments on additional diseases suggested for designation to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1300, *Katherine.Schumann@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:

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I. Background: Priority Review Voucher Program

Section 524 of the FD&C Act (21 U.S.C. 360n), which was added by section 1102 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), uses a PRV incentive to encourage the development of new drugs for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. To be eligible to receive a tropical disease PRV, a drug must be for a ''tropical disease'' as listed under section 524(a)(3) of the FD&C Act. This list can be expanded by the Agency under section 524(a)(3)(S) of the FD&C Act, which authorizes FDA to designate by order ''[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations'' as an addition to the tropical disease list. Further information about the tropical disease PRV program can be found in the guidance for industry ''Tropical Disease Priority Review Vouchers,'' available at *https://www.fda.gov/media/72569/download.*

On August 20, 2015, FDA published a final order (80 FR 50559) (August 2015 final order) designating Chagas disease and neurocysticercosis as additions to the list of tropical diseases eligible for PRV consideration. This final order also set forth FDA's interpretation of the statutory criteria for tropical disease designation and expands the list of tropical diseases under section 524(a)(3)(S) of the FD&C Act. Additions by order to the statutory list of tropical diseases published in the **Federal Register** can be accessed at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.*

In this document, FDA has applied its August 2015 criteria as set forth in the final order for analyzing whether the zoonotic infection brucellosis meets the statutory criteria for addition to the tropical disease list.

II. Disease Being Designated

FDA has considered all diseases submitted to the public docket (FDA–2008–N–0567) between October 1, 2018, and June 30, 2019, as potential additions to the list of tropical diseases under section 524 of the FD&C Act, pursuant to the docket review process explained on the Agency's website at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.* Based on an assessment using the criteria from its August 2015 final order, FDA has determined that brucellosis will be designated as an addition to the list of ''tropical diseases'' under section 524 of the FD&C Act.

Brucellosis is one of the most common zoonotic infections, meaning it is transmissible from animals to humans. The species most commonly associated with human disease are *B. abortus, B. melitensis, B. suis,* and, rarely, *B. canis.* Brucellosis occurs in greater than 500,000 individuals worldwide annually through contact with fluids or inhalation of aerosols from infected wild or domestic animals (including sheep, cattle, goats, pigs and other animals) or ingestion of food products derived from infected animals, such as undercooked meat or unpasteurized milk and cheese (Refs. 1 and 2). Brucellosis can cause significant morbidity in both humans and animals. FDA's rationale for adding this disease to the list is discussed in the analyses that follow.

Efforts to control infections caused by *Brucella* spp. in livestock in high-income countries have led to a notable drop in human infections but brucellosis continues to cause a significant burden of disease in developing countries (Ref. 3). Severity of disease can vary widely, from asymptomatic disease to moderate illness with acute fever, malaise, and weight loss, to more severe illnesses including meningitis, endocarditis, osteomyelitis, and pneumonitis (Refs. 4 and 5). With appropriate therapy, brucellosis rarely causes death. Chronic infections with *Brucella* spp. cause granulomatous disease that can affect any organ, leading to chronic debilitating symptoms including arthritis, uveitis, and neuropsychiatric abnormalities (Ref. 6). In pregnant women, *Brucella* spp. infections are associated with a high risk of spontaneous abortion, miscarriage, and fetal death (Ref. 1). The incubation

period is highly variable, usually 1 to 4 weeks, but may be as long as 6 months.

The treatment regimens for adults with uncomplicated brucellosis have changed little in 30 years. There are currently three FDA approved treatments for brucellosis: Doxycycline, streptomycin, and tetracycline (Refs. 7, 8, and 25). Prolonged treatment (greater than 6 weeks) with two or more antimicrobials are generally required, and relapses occur in 5 to 15 percent of patients (Refs. 9 and 10). While an effective vaccine exists for brucellosis in livestock (Ref. 11), there are no vaccines licensed in the United States for human use.

A. No Significant Market in Developed Nations

No significant direct market exists for the prevention or treatment of brucellosis in developed nations. In high-income countries, the direct market for products to prevent brucellosis in humans is small due to the success of strategies to decrease human exposure through control efforts in livestock and food. The incidence in the United States is 0.4 cases per million with approximately 100 cases of brucellosis in humans reported annually (Ref. 12). Three-quarters of these cases are due to *B. melitensis* or *B. abortus* associated with ingestion of unpasteurized dairy products from countries where the disease remains endemic (Ref. 1). Brucellosis has been significantly reduced or eliminated in Northern Europe. For example, in Germany, 22 to 47 annual cases were reported between 2010 and 2015, with most cases occurring following travel or consumption of contaminated imported products (Ref. 13).

Brucellosis is considered endemic in some Mediterranean countries that are designated as high income by the World Bank; presence on the World Bank's list, FDA determined in the August 2015 final order, will be used as evidence that such a country should be considered a ''developed nation'' for tropical disease determination (Ref. 14). These high-income countries include Greece (20.9 cases per million of population per year), Spain (15.1), and Portugal (13.9). However, the annual incidence of brucellosis in these countries is considerably lower than in Turkey (262.2) and the Republic of North Macedonia (148), which are not on the World Bank list of high-income economies (Ref. 15). Saudi Arabia, classified by the Word Bank as high-income, has a reported annual incidence of brucellosis of 214.4 per million of population (Ref. 15). Within Latin America, Mexico is a prominent reservoir of human brucellosis, with an annual incidence of 28.7 cases per million of population, while Panama and Argentina, both on the World Bank list of high-income countries, have a lower rate of disease at 10.1 and 8.4 cases per million of population per year, respectively (Ref. 15).

The characteristics of specific diseases under consideration may affect the measures of occurrence used to estimate the likely market for interventions. As described in the August 2015 final order, FDA has used a disease prevalence rate of 0.1 percent of the population in developed countries for aiding in the determination of whether a ''significant market'' may exist for treatment of a disease. In this order, incidence rather than prevalence was considered to provide a better estimate of market size. Incidence measures new cases that are diagnosed in a population in a given time period. In an acute disease such as brucella, that can be resolved through treatment, incidence represents a reasonable indicator for the number of cases that would be treated in a given year and provides a better estimate of market size. As noted in the August 2015 final order, ''[t]he market for many FDA-approved products includes situations in which individuals (often reimbursed by their insurers) purchase the products for use by a specific patient. This reflects what we will refer to as the 'direct' market, and the direct market for a drug in a developed country can often by estimated by assessing the occurrence of a particular disease in that country.'' Even in countries designated by the World Bank as high-income where the disease is considered endemic, the incidence is well below 0.1 percent of the population; therefore, the direct market for products to prevent or treat brucellosis in humans would be small. These markets are unlikely to provide sufficient incentive to encourage development of products to treat or prevent brucellosis.

No significant indirect market exists for the treatment or prevention of brucellosis in developed nations. The U.S. Centers for Disease Control and Prevention (CDC) has designated *Brucella* spp. *B. suis, B. melitensis,* and *B. abortus* as select agents, a subset of biological agents and toxins that may pose a severe threat to public health, due to the ease of aerosolization, low infectious dose, and difficulty in diagnosis; and the CDC, U.S. Department of Agriculture, and U.S. Department of the Interior, have identified brucellosis as one of eight diseases of greatest national concern that should be addressed jointly by Federal zoonotic disease programs (Refs. 1 and 16). Despite these designations, at present FDA is unaware of any significant funding for drug development targeting treatment or prophylaxis of brucellosis by U.S. government sources. Further, *Brucella* spp. are not listed as a high priority threat in the 2017–2018 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (Ref. 17).

Given the above information, it is reasonable to conclude that no significant market exists in developed nations for the prevention or treatment of brucellosis in humans.

B. Disproportionately Affects Poor and Marginalized Populations

While brucellosis is not currently designated by the World Health Organization (WHO) as a neglected tropical disease, WHO has identified it as a neglected zoonotic disease (Ref. 18). Successful animal vaccination programs for brucellosis require sustained implementation over several years. Largely eliminated in developed nations, brucellosis disproportionally affects poor and marginalized populations in endemic countries where inadequate control measures maintain an ongoing reservoir of disease in animals. Brucellosis remains significant in many parts of the world, including some countries in the Mediterranean Basin, Africa, the Middle East, Asia, and Central and South America (Refs. 1 and 19). The reemergence of brucellosis in the Balkans and, more recently, some parts of the Middle East suggests that geopolitical factors could be important drivers of the disease (Refs. 20 and 21).

Illnesses caused by *Brucella* spp. result in significant morbidity with disproportionate impact on marginalized populations. Transmission of brucellosis to humans occurs most frequently in individuals who consume infected meat or unpasteurized dairy products, exposures that occur more commonly in resource-poor regions. Efforts to control *Brucella* spp. in humans in low-income countries using methods employed in high income nations, such as vaccination of livestock, have had limited success due to insufficient veterinary resources and high infection rates in wild animal populations (Ref. 22). In addition, routine pasteurization of dairy products tends to be less common in developing countries (Ref. 3).

Human infection with *Brucella* spp. results in significant losses in work days, lowering income and often the socioeconomic status of affected

individuals and their families (Ref. 3). A Disability-Adjusted Life Years (DALY) weighting for acute brucellosis is similar to an episode of malaria (Refs. 6 and 23). DALY burdens for brucellosis have not been calculated, however, in part due to the difficulty in obtaining accurate surveillance data in affected low-income countries (Ref. 22).

As mentioned above, prolonged treatment courses of greater than 6 weeks with two or more antimicrobials are generally required. These recommended treatment regimens pose special challenges for resource-poor countries (Ref. 24).

The above information demonstrates it is reasonable to conclude that brucellosis disproportionately affects poor and marginalized populations.

Given the factors described above, FDA has determined that brucellosis meets both the statutory criteria of ''no significant market in developed nations'' and ''disproportionately affects poor and marginalized populations.'' Therefore, FDA is designating brucellosis as an addition to the tropical disease list under section 524 of the FD&C Act.

III. Process for Requesting Additional Diseases To Be Added to the List

The purpose of this order is to add brucella to the list of tropical diseases that FDA has found to meet the criteria in section 524(a)(3)(S) of the FD&C Act. By expanding the list to include brucellosis with this order, FDA does not mean to preclude the addition of other diseases to this list in the future. Interested persons may submit requests for additional diseases to be added to the list to the public docket established by FDA for this purpose (see *https://www.regulations.gov,* Docket No. FDA–2008–N–0567). Such requests should be accompanied by information to document that the disease meets the criteria set forth in section 524(a)(3)(S) of the FD&C Act. FDA will periodically review these requests, and, when appropriate, expand the list. For further information, see FDA's Tropical Disease Priority Review Voucher Program web page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.*

IV. Paperwork Reduction Act

This final order reiterates the ''open'' status of the previously established public docket through which interested persons may submit requests for additional diseases to be added to the list of tropical diseases that FDA has found to meet the criteria in section 524(a)(3)(S) of the FD&C Act. Such a request for information is exempt from Office of Management and Budget review under 5 CFR 1320.3(h)(4) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Specifically, ''[f]acts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof'' are exempt, ''provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment.''

V. 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 are also 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.

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11. * U. S. Department of Agriculture, Animal and Plant Health Inspection Service, ''Facts About Brucellosis,'' cited June 19, 2019, *https://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/downloads/bruc-facts.pdf.*
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13. Norman, F.F., B. Monge-Maillo, S. Chamorro-Tojeiro, et al., 2016, ''Imported Brucellosis: A Case Series and Literature Review,'' *Travel Medicine and Infectious Diseases,* epub ahead of print May 13, 2016, doi: 10.1016/j.tmaid.2016.05.005.
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Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15254 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–1066; FDA–2019–E–1067; and FDA–2019–E–1068]

Determination of Regulatory Review Period for Purposes of Patent Extension; ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 14, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 11, 2021. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 14, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 14, 2020. 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 Nos. FDA–2019–E–1066, FDA–2019–E–1067; and FDA–2019–E–1068 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM.'' 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM. ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM is indicated in conjunction with cataract surgery for the reduction of intraocular pressure in adult patients with mild to moderate primary open angle glaucoma. Subsequent to this approval, the USPTO received patent term restoration applications for ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (U.S. Patent Nos. 7,867,186; 9,301,875; and 9,597,230) from Glaukos Corporation, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated June 21, 2019, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM is 2,508 days. Of this time, 2,330 days occurred during the testing phase of the regulatory review period, while 178 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* August 11, 2011. FDA has verified the applicant's claim that the date the investigational device exemption for human tests to begin, as required under section 520(g) of the FD&C Act became effective, was August 11, 2011.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* December 26, 2017. The applicant claims December 21, 2017, as the date the premarket approval application (PMA) for ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (PMA 170043) was initially submitted. However, FDA records indicate that PMA 170043 was submitted on December 26, 2017.

3. *The date the application was approved:* June 21, 2018. FDA has verified the applicant's claim that PMA 170043 was approved on June 21, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,345 days, 496 days, or 1,783 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15295 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3769]

Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act.'' Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the FDA Reauthorization Act of 2017 (FDARA) require that certain pre-submissions and submissions for devices be submitted in

electronic format specified by FDA beginning on such date as specified in final guidance. It also mandates that FDA issue draft guidance not later than October 1, 2019, and a final guidance not later than 1 year after the close of the public comment period, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter from the Secretary of Health and Human Services to Congress, FDA committed to developing electronic submission templates, and issuing a draft guidance on the topic. No later than 12 months after the close of the public comment period, the Agency will issue a final guidance. This guidance is intended to satisfy the final guidance documents referenced in the FDA&C Act and the MDUFA IV Commitment Letter.

DATES: The announcement of the guidance is published in the **Federal Register** on July 15, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidance documents 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–3769 for ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act.'' 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 § 10.115 (21 CFR 10.115(g)(5))).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 request.

FOR FURTHER INFORMATION CONTACT: Jacqueline Gertz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1655, Silver Spring, MD 20993–0002, 240–402–9677 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 745A(b) of the FD&C Act (21 U.S.C. 379k–1(b)), amended by section 207 of FDARA (Pub. L. 115–52), requires that pre-submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of the FD&C Act (21 U.S.C. 360(k), 360c(f)(2)(A), 360e(c), 360e(d), 360e(f), 360j(g), 360j(m), or 360bbb–3) or section 351 of the Public Health Service Act (42 U.S.C. 262) and any supplements to such pre-submissions or submissions, including appeals of those submissions, be submitted in electronic format specified by FDA beginning on such date as specified by FDA in final guidance. It also mandates that FDA issue a draft guidance not later than

October 1, 2019, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. In addition, in the MDUFA IV Commitment Letter [1] from the Secretary of Health and Human Services to Congress, FDA committed to developing ''electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process'' and ''by FY [fiscal year] 2020, the Agency will issue a draft guidance document on the use of the electronic submission templates.'' No later than 12 months after the close of the public comment period, the Agency will issue a final guidance. This guidance is intended to satisfy the final guidance documents referenced in section 745A(b)(3) of the FD&C Act and the MDUFA IV Commitment Letter.

The Agency has concluded that it is not feasible to describe and implement the electronic format(s) that would apply to all the submissions covered by section 745A(b) of the FD&C Act in one guidance document. Accordingly, this guidance describes how FDA interprets and plans to implement the requirements of section 745A(b)(3) of the FD&C Act, while individual guidances will be developed to specify the formats for specific submissions and corresponding timetables for implementation. Specifically, this guidance discusses: (1) The submission types that must be submitted electronically, (2) criteria for waivers of and exemptions from the submissions in electronic format requirements, and (3) the timetable and process for implementing the requirements.

A notice of availability for the draft guidance appeared in the **Federal Register** of November 25, 2019 (84 FR 50850). FDA considered the comments received and revised the guidance as appropriate in response to the comments, including an update to add real-time review Premarket approval application (PMA) supplements and a clarification that we intend to consider the time period necessary to transition to use of the electronic format when identifying the date on which electronic format will be required.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this document provides such requirements under section 745A(b)(3) of the FD&C Act (*i.e.,* standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as must or required, this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. (See § 10.115(d).)

However, this document also contains guidance on additional submission types for which submission in electronic format is not required. To the extent that this guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3), it is being issued in accordance with FDA's good guidance practices regulation (§ 10.115). This guidance represents the Agency's current thinking on this topic, and do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used for these recommendations if such an approach satisfies the requirements of the applicable statutes and regulations. This final guidance contains both binding and nonbinding provisions.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance is also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19031 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket Notification Submission	0910–0120
814, subparts A through E	Premarket Approval Application	0910–0231
814, subpart H	Humanitarian Use Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo Classification Process	0910–0844
''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act''.	513(g) Request for Information	0910–0705
''Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff''.	Pre-Submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

[1] *https://www.fda.gov/media/102699/download.*

21 CFR part or guidance	Topic	OMB control No.
''Humanitarian Device Exemption Regulation: Q&As''	Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements.	0910–0661
''Emergency Use Authorization of Medical Products''	Emergency Use Authorization	0910–0595
601	Biologics License Applications	0910–0338
''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Waiver Applications	0910–0598
''Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization''.	Administrative Procedures for CLIA Categorizations	0910–0607

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15250 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1396]

Use of Data From Foreign Investigational Studies To Support Effectiveness of New Animal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #265 entitled ''Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs.'' The draft guidance, if finalized, will describe FDA's current thinking with respect to assisting sponsors in incorporating data from foreign countries into proposed clinical investigational protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by October 13, 2020 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–2020–D–1396 for ''Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal 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 the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See

the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Storey, Center for Veterinary Medicine (HFV–131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0578, *susan.storey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #265 entitled ''Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs.'' Section 305 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (Pub. L. 115–234), among other things, directed FDA to hold a public meeting for interested parties to discuss innovative animal drug investigation designs and to issue guidance addressing the incorporation of the use of such elements of investigations as complex adaptive and other novel investigation designs, data from foreign countries, real-world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints into clinical investigation protocols and applications to support the effectiveness of new animal drugs.

In the **Federal Register** of July 9, 2019 (84 FR 32749), FDA's Center for Veterinary Medicine (CVM) published a notice of a public meeting entitled ''Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs'' giving interested persons until August 17, 2019, to comment on the topics discussed at the public meeting and the questions published in the meeting notice (84 FR 32749 at 32750–32751).[1] On August 13, 2019, we published a notice announcing the extension of the comment period to September 16, 2019 (84 FR 40071). CVM received numerous comments on the topics discussed at the public meeting and the questions published in the meeting notice and those comments were considered as the draft GFI #265 entitled ''Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs'' was developed.

This draft guidance describes principles for designing, conducting, and reporting the results for investigations or studies, including data from foreign countries, in submissions to CVM to demonstrate substantial evidence of effectiveness for new animal drug applications or a reasonable expectation of effectiveness for applications for conditional approval of a new animal drug. It also describes how sponsors may obtain feedback from CVM regarding the incorporation of data from foreign countries into investigations and study protocols before the submission of an application. FDA is committed to supporting data that may be recognized globally in order to enhance animal drug development, facilitate the use of foreign data, and minimize the need to conduct duplicative studies.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the current thinking of FDA regarding the use of data from foreign investigational studies to support the effectiveness of new animal 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

FDA tentatively concludes that this draft guidance contains no 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 draft guidance refers to previously approved FDA collections of information found in FDA regulations for new animal drug applications submitted under sections 512(b) (21 U.S.C. 360b(b)) and 571 (21 U.S.C. 360ccc) of the FD&C Act. These collections of information are subject to review by the OMB under the PRAct. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15242 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

[1] *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/public-meeting-incorporating-alternative-approaches-clinical-investigations-new-animal-drugs.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0567]

Notice of Decision Not To Designate Clonorchiasis as an Addition to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency), in response to suggestions submitted to the public docket FDA–2008–N–0567, between June 20, 2018, and November 21, 2018, has analyzed whether the foodborne trematode infection clonorchiasis meets the statutory criteria for designation as a ''tropical disease'' for the purposes of obtaining a priority review voucher (PRV) under the Federal Food, Drug, and Cosmetic Act (FD&C Act), namely whether it primarily affects poor and marginalized populations and whether there is ''no significant market'' for drugs that prevent or treat clonorchiasis in developed countries. The Agency has determined at this time that clonorchiasis does not meet the statutory criteria for addition to the tropical diseases list under the FD&C Act. Although clonorchiasis disproportionately affects poor and marginalized populations, it is an infectious disease for which there is a significant market in developed nations; therefore, FDA declines to add it to the list of tropical diseases.

DATES: July 15, 2020.

ADDRESSES: Submit electronic comments on additional diseases suggested for designation to *https://www.regulations.gov.* Submit written comments on additional diseases suggested for designation to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1300, *Katherine.Schumann@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

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I. Background: Priority Review Voucher Program

Section 524 of the FD&C Act (21 U.S.C. 360n), which was added by section 1102 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), uses a PRV incentive to encourage the development of new drugs, including biological products, for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. Further information about the tropical disease PRV program can be found in the October 6, 2016 (81 FR 69537) guidance for industry ''Tropical Disease Priority Review Vouchers,'' available at *https://www.fda.gov/media/72569/download.* Additions to the statutory list of tropical diseases by an FDA final order published in the **Federal Register** can be accessed at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.*

On August 20, 2015, FDA published a final order (80 FR 50559) (August 2015 final order) designating Chagas disease and neurocysticercosis as additions to the list of tropical diseases under section 524 of the FD&C Act. The August 2015 final order also set forth FDA's interpretation of the statutory criteria for designating additions to the section 524 list of tropical diseases and expands the list of tropical diseases under section 524(a)(3)(R) of the FD&C Act. That section, later redesignated as section 524(a)(3)(S) of the FD&C Act, authorizes FDA to designate by order ''[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations'' as a tropical disease for which approved drug applications may be eligible for a PRV.

FDA has applied its criteria as set forth in the August 2015 final order to analyze whether clonorchiasis meets the statutory criteria for addition to the tropical diseases list. As discussed below, the Agency has determined that clonorchiasis does not meet the statutory criteria for designation as a PRV-eligible ''tropical disease'' under section 524 of the FD&C Act; thus, FDA will not add it to the list of tropical diseases whose applications may be eligible for a priority review voucher.

II. Decision Not To Designate Clonorchiasis

FDA has considered all disease suggestions submitted to the public docket (FDA–2008–N–0567) between June 20, 2018, and November 21, 2018, as potential additions to the list of tropical diseases under section 524 of the FD&C Act, under the docket review process explained on the Agency's web page at *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm534162.htm.* Based on an assessment of currently available information, and using the criteria from its August 2015 final order, FDA has determined that clonorchiasis will not be designated as a ''tropical disease'' for purposes of the tropical disease PRV program under section 524 of the FD&C Act.

A. Clonorchiasis

Clonorchiasis is caused by *Clonorchis sinensis,* trematodes (parasitic flatworms), also known as flukes, which are acquired by humans through the consumption of raw or undercooked fish (Ref. 1). The natural final hosts of *C. sinensis* are dogs and other fish-eating carnivores (Ref. 2). *C. sinensis* are reported in the Democratic People's Republic of Korea (North Korea), the Republic of Korea (South Korea), China, Taiwan, Vietnam, Japan, and the Russian Far East (Ref. 1).

The final location of adult *C. sinensis* is the smaller bile ducts of the liver (Ref. 2). The symptoms of clonorchiasis are related to inflammation and fibrosis of the tissues adjacent to bile ducts. While the majority of infected individuals are asymptomatic, patients may develop cholangitis, intrahepatic calculi, or cholangiohepatitis (Ref. 2). Chronic infection is also associated with the development of cholangiocarcinoma, a severe and fatal form of bile duct cancer, and *C. sinensis* is recognized by the International Agency for Research on Cancer (IARC) as Group 1, which means that the agent is classified as carcinogenic to humans (Refs. 3 and 4).

There is one FDA approved treatment for clonorchiasis, praziquantel, approved in 1982 and indicated for the treatment of infections due to all species of schistosoma and infections due to the liver flukes *C. sinensis* and *Opisthorchis viverrini* (Ref. 5).

1. Significant Market in Developed Nations

FDA was unable to make the determination that no significant market exists for the treatment or prevention of clonorchiasis in developed nations, as the most recent data shows significant prevalence of clonorchiasis in a developed nation. As stated above, clonorchiasis occurs as a result of infection by *C. sinensis,* which has been reported in North Korea, South Korea, China, Taiwan, Vietnam, Japan, and the Russian Far East. The limited range of *C. sinensis* means that individuals are infected only in those countries noted, and infections in other countries only occur from the movement of infected persons. North Korea, China, Vietnam, and the Russian Federation (Russia) are not on the World Bank's list of high-income countries (Ref. 6). However, South Korea, Japan, and Taiwan are high-income economies, based on World Bank's list of high-income countries, and therefore are considered developed countries for purposes of this order (Ref. 6).

In the developed countries where *C. sinensis* is found, clonorchiasis rates are typically low. *C. sinensis* was endemic in Japan throughout the 1950s; however, improved hygiene associated with modernization and industrialization has reduced its incidence in humans in the country to a negligible level (Ref. 7). Likewise, in Taiwan, *C. sinensis* has been nearly eliminated from all but a small number of poor rural areas (Refs. 8 and 9). However, as of 2008, South Korea had an estimated 1.4 million people infected with *C. sinensis.* Based on data from 1981, the egg-positive proportion of people living near 7 major rivers was 22 percent among 13,373 examined, varying from 0.6 percent to 45.5 percent (Ref. 10). The persistence of *C. sinensis* infection is thought to be primarily due to difficulties in changing the traditional habit of eating raw freshwater fish (Refs. 10 and 11). The 2017 South Korean population was 51.42 million, and using the most recent estimate of 1.4 million people infected with *C. sinensis,* the estimated prevalence of *C. sinensis* infection in South Korea is over 2 percent of the population (Ref. 12). This prevalence is higher than 0.1 percent of the population of South Korea. The 0.1 percent of the population was discussed in FDA's order of 2015 as a factor for aiding in the determination of whether a significant market may exist for a disease's treatment. FDA worked to find a more recent prevalence rate for clonorchiasis infections in South Korea but was unsuccessful. If more recent

prevalence information is publicly accessible, please provide this information to the Dockets Management Staff for Docket No. FDA–2008–N–0567 (see **ADDRESSES**) and the Agency will reevaluate our findings.

There is currently no estimate of the number of individuals with clonorchiasis in the United States. Of the infections that do occur in the United States, foodborne trematode infections occur predominantly in immigrants and travelers from endemic regions (Refs. 13 and 14). For example, in a retrospective study in one U.S. travel medicine clinic over 6 years, only 17 cases of *Opisthorchis spp.* and *Clonorchis spp.* were identified through the review of ova and parasite records (Ref. 15). All patients with identified cases were migrants from Laos, Cambodia, Thailand, Vietnam, the former Soviet Union, and Ecuador (Ref. 15).

There is evidence that U.S. military personnel were exposed to *Opisthorchis spp.* and *Clonorchis spp.* during their service in the Vietnam War (Ref. 16). In one study, there was evidence that veterans were likely previously infected, but patients in the study did not have evidence of ongoing infection given negative stool exams and negative imaging studies, and therefore would not have ongoing infections requiring treatment now (Ref. 16).

As illustrated above, clonorchiasis occurs rarely in most developed nations. However, in South Korea, the prevalence was 1.4 million people infected as of 2008, which may offer an incentive to drive development of new drug products to treat or prevent clonorchiasis.

2. Clonorchiasis Disproportionately Affects Poor and Marginalized Populations

Clonorchiasis disproportionately affects poor and marginalized populations around the world. As areas where clonorchiasis occurs develop economically, the epidemiology of clonorchiasis changes, and fewer cases of clonorchiasis occur. This is supported by data in Japan and Taiwan where incidences of clonorchiasis have fallen rapidly with improved hygiene as the countries have developed (Refs. 7 and 8).

Transmission of foodborne trematodes within countries is typically restricted to limited areas and reflects behavioral and ecological patterns that are related to socioeconomic status. This includes people's food habits, methods of food production and preparation, and the distribution of intermediate hosts. For example, food can be contaminated through unhygienic preparation and storage. Furthermore, the consumption of raw fish and crustaceans is a main risk factor for contracting these parasites. The parasite's life cycle is closely linked with water and sanitation. In populations without access to toilets, or without sewage system infrastructure, unprocessed human and animal fecal waste may be found near water or used as manure or fish feed. This can contaminate drinking water and aquatic vegetables, leading to a continuous cycle of infections.

Clonorchiasis is included in the World Health Organization (WHO) List of Neglected Tropical Diseases (Ref. 17). The WHO Foodborne Disease Burden Epidemiology Reference Group identified clonorchiasis as an important cause of disability, with an estimated annual incidence of over 31,620 infections and 5,770 deaths, resulting in global disability adjusted life years, which is calculated by adding the number of years of life lost to mortality and the number of years lived with disability due to morbidity due to the illness, of 522,863 (Ref. 18). Given the above information, it is reasonable to conclude that clonorchiasis disproportionately affects poor and marginalized populations.

B. FDA Determination

In sum, although clonorchiasis disproportionately affects poor and marginalized populations, it is an infectious disease that fails to meet the statutory criterion for ''no significant market in developed nations.'' FDA has determined that, at this time, the available information does not support a determination that clonorchiasis meets the statutory criteria in section 524 of the FD&C Act for addition to the list of tropical diseases.

III. Process for Requesting Additional Diseases To Be Added to the List

FDA's current determination regarding clonorchiasis does not preclude interested persons from requesting its consideration in the future. To facilitate the consideration of future additions to the list, FDA established a public docket (see *https://www.regulations.gov,* Docket No. FDA–2008–N–0567) through which interested persons may submit requests for additional diseases to be added to the list. Such requests should be accompanied by information to document that the disease meets the criteria set forth in section 524(a)(3)(S) of the FD&C Act. FDA will periodically review these requests, and, when appropriate, expand the list. For further information, see FDA's Tropical Disease Priority Review Voucher Program web page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.*

IV. Paperwork Reduction Act

This notice reiterates the ''open'' status of the previously established public docket through which interested persons may submit requests for additional diseases to be added to the list of tropical diseases that FDA has found to meet the criteria in section 524(a)(3)(S) of the FD&C Act. Such a request for information is exempt from Office of Management and Budget review under 5 CFR 1320.3(h)(4) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Specifically, ''[f]acts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof'' are exempt, ''provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the full consideration of the comment.''

V. 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. *U.S. Centers for Disease Control and Prevention, 2018, ''Parasites—Clonorchis: Epidemiology & Risk Factors,'' accessed October 24, 2019, *https://www.cdc.gov/parasites/clonorchis/epi.html.*
2. *WHO, 2018, ''Fact Sheet on Foodborne Trematodiases,'' accessed October 23, 2019, *https://www.who.int/news-room/fact-sheets/detail/foodborne-trematodiases.*
3. *WHO, IARC, 2019, ''IARC Monographs on the Identification of Carcinogenic Hazards to Humans, Agents Classified by the IARC Monographs,'' Vols. 1–125, accessed October 23, 2019, *https://monographs.iarc.fr/agents-classified-by-*

the-iarc/.
4. *WHO, IARC, 2012, ''IARC Monographs on the Evaluation of Carcinogenic Risks in Humans, Opisthorchis Viverrini and Clonorchis Sinensis,'' Vol. 100B, 341–370, accessed October 23, 2019, *https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100B-13.pdf.*
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15. Stauffer, W.M., J.S. Sellman, and P.F. Walker, 2004, ''Biliary Liver Flukes (Opisthorchiasis and Clonorchiasis) in Immigrants in the United States: Often Subtle and Diagnosed Years After Arrival,'' *Journal of Travel Medicine,* 11(3):157–159.
16. Psevdos, G., F.M. Ford, and S.T. Hong, 2018, ''Screening US Vietnam Veterans for Liver Fluke Exposure 5 Decades After the End of the War,'' *Infectious Diseases in Clinical Practice,* epub ahead of print January 16, 2018, doi: 0.1097/IPC.0000000000000611.
17. *WHO, 2018, ''Neglected Tropical Diseases,'' accessed October 24, 2019, *https://www.who.int/neglected_diseases/diseases/en/.*
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Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15253 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0567]

Notice of Decision Not To Designate Coccidioidomycosis as an Addition to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency), in response to suggestions submitted to the public docket number FDA–2008–N–0567 between October 1, 2018, and June 30, 2019, has analyzed whether coccidioidomycosis meets the statutory criteria for designation as a tropical disease for the purposes of obtaining a priority review voucher (PRV) under the Federal Food, Drug, and Cosmetic Act (FD&C Act), namely whether it primarily affects poor and marginalized populations, and whether there is ''no significant market'' for drugs that prevent or treat coccidioidomycosis infections in developed countries. The Agency has determined that coccidioidomycosis does not meet the statutory criteria for designation as a tropical disease eligible for PRV consideration because of the potential market for preventive products (such as vaccines), and therefore declines to designate it as an addition to the list of tropical disease PRV-eligible diseases at this time.

DATES: July 15, 2020.

ADDRESSES: Submit electronic comments on additional diseases suggested for designation to *https://www.regulations.gov.* Submit written comments on additional diseases suggested for designation to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1300, *Katherine.Schumann@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:

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I. Background: Priority Review Voucher Program

Section 524 of the FD&C Act (21 U.S.C. 360n), which was added by section 1102 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), uses a PRV incentive to encourage the development of new drugs, including biological products, for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. Further information about the tropical disease PRV program can be found in the guidance for industry ''Tropical Disease Priority Review Vouchers,'' available at *https://www.fda.gov/media/72569/download.* Section 524(a)(3) of the FD&C Act includes a list of infectious diseases, applications for the prevention or treatment of which may be eligible to qualify for a PRV, and Congress has amended that list multiple times to add new diseases since section 524 was first enacted. Additions to the statutory list of PRV-eligible tropical diseases by an FDA final order published in the **Federal Register** can be accessed at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.*

On August 20, 2015, FDA published a final order (80 FR 50559) (August 2015 final order) designating Chagas disease and neurocysticercosis as additions to the list of tropical diseases under section 524 of the FD&C Act. The August 2015 final order also set forth

FDA's interpretation of the statutory criteria for designating additions to the section 524 list of tropical diseases and expands the list of tropical diseases under section 524(a)(3)(R) of the FD&C Act. That section, later redesignated as section 524(a)(3)(S) of the FD&C Act, authorizes FDA to designate by order ''[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations'' as a tropical disease for which approved drug applications may be eligible for a PRV.

FDA has applied its criteria as set forth in the August 2015 final order to analyze whether the fungal infection coccidioidomycosis meets the statutory criteria for addition to this tropical disease list. As discussed below, the Agency has determined that coccidioidomycosis does not meet the statutory criteria for designation as a PRV-eligible ''tropical disease'' under section 524 of the FD&C Act because of the potential market for preventive measures such as vaccines. Thus, FDA will not add it to the list of tropical diseases whose applications may be eligible for a priority review voucher at this time.

II. Decision Not To Designate Coccidioidomycosis

FDA has considered all disease suggestions submitted to the public docket (FDA–2008–N–0567) between October 1, 2018, and June 30, 2019, as potential additions to the list of tropical diseases under section 524 of the FD&C Act, under the docket review process explained on the Agency's web page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.* Based on an assessment of currently available information, and using the criteria from its August 2015 final order, FDA has determined that coccidioidomycosis does not currently fulfill the criteria for addition to the list of diseases eligible for the tropical disease PRV program under section 524 of the FD&C Act and is not designating it as an addition to the list at this time.

A. Coccidioidomycosis

Coccidioidomycosis, also known as ''Valley fever,'' is a systemic fungal infection caused by inhalation of *Coccidioides* spp. spores. Major areas of endemicity include substantial parts of the southwestern United States. The fungus occurs in the environment, especially in certain soil types in hot, dry climates, and inhalation may occur after environmental disturbance such as soil disruption and wind. The species most commonly associated with disease are *C. immitis,* which is endemic to parts of California, and *C. posadasii,* which is found in Arizona, Utah, Texas, regions of Mexico, and Central and South America (Ref. 1). Most reported cases occur in individuals who live in or have traveled to endemic areas. From 1990 to 2011, the incidence of reported coccidioidomycosis in the United States increased greater than 8-fold in areas of endemicity (Ref. 2).

Manifestations of infection with *Coccidioides* spp. can range from subclinical (estimated at one-half to two-thirds of infections), that might not be detected unless the person is included in a skin test survey or serologic screening, to acute self-limited respiratory illness that may be difficult to distinguish from other acute respiratory infections, to severe disease with chronic or life-threatening complications (Ref. 3). Acute respiratory coccidioidomycosis has a 1- to 3-week incubation period and most commonly presents as a self-limited illness with fever, muscle pain, cough, rash, weight loss, and malaise (Ref. 4). In areas where the illness is highly endemic, upwards of 30 percent of community-acquired pneumonia cases may be caused by *Coccidioides* spp. (Ref. 5). Five to ten percent of affected patients develop severe or chronic lung disease such as cavitary pneumonia, nodules, and bronchiectasis, and in approximately one percent of patients, infection disseminates to the central nervous system, skin, joints, or bone. Individuals older than 65 years, smokers, and those with diabetes are at increased risk of pulmonary complications of coccidioidomycosis, while those with depressed cellular immune function (Refs. 6 and 7), pregnant women (Ref. 8), or persons of African or Asian descent have an elevated risk of disseminated disease (Ref. 9). Coccidioidal meningitis cannot be reliably cured with current antifungal therapy and has a mortality rate of approximately 30 percent (Ref. 10). Although the public health burden attributable to coccidioidomycosis in the United States is primarily due to morbidity, an estimated 200 coccidioidomycosis-associated deaths occur each year (Ref. 11).

Treatment recommendations depend upon the severity, location, and dissemination of the disease as well as the underlying immune status of the patient (Ref. 12). A 2016 publication of professional society guidelines recommends against antifungal therapy in patients with newly diagnosed, uncomplicated coccidioidal pneumonia, with mild or resolved symptoms, and without immunosuppressive conditions, advising that such patients receive supportive measures such as physical therapy and close monitoring. In individuals with severe disease or disseminated disease, these guidelines advise antifungal therapy for a minimum of 3 to 6 months with an azole (fluconazole or itraconazole), intravenous amphotericin B, or both. Patients with immunocompromise or other underlying conditions may require therapy for 12 months or longer. In individuals with meningitis due to *Coccidioides* spp., these guidelines recommend treatment for life (Ref. 13).

There are two FDA-approved treatments for coccidioidomycosis: Amphotericin B deoxycholate, available in brand or generic form, and ketoconazole. In 2013, FDA warned that ketoconazole should not be used as a first-line therapy for any fungal infection as it can cause severe liver injury, adrenal insufficiency, and harmful drug interactions, and should be prescribed only for endemic mycoses, such as coccidioidomycosis, when alternative antifungal therapies are not available or tolerated (Ref. 14). With respect to preventative products, no vaccines have yet been developed that protect persons from developing infection or progressing from infection to disease due to *C. immitis,* but potential for development of such vaccines has been a topic of interest in some expert discussions as outlined in the next section.

1. Significant Market in Developed Nations

In the August 2015 final order, FDA interpreted the statutory criterion ''no significant market'' to refer to the market for drugs for the treatment or prevention of infectious diseases. The August 2015 final order states, ''[b]ecause the statute offers vouchers for applications for drugs for either the treatment or prevention of infectious diseases, it is reasonable to assume that 'no significant market' can refer to drugs for the treatment or prevention of infectious diseases. Thus, FDA will analyze the market for drugs for both the treatment and prevention of infectious diseases for a particular infectious disease.'' In other words, if there is a significant market for either the treatment or prevention of the infectious disease, the criterion that there be ''no significant market'' in developed nations is not met.

The relative importance of prevention markets may vary in part according to whether most cases of a particular disease in developed countries are attributable to exposure in those same

countries (or would be in the absence of a preventive product such as vaccine) or to movement between countries of persons exposed elsewhere, because preventive measures may be more widely important if exposure could be local and unavoidable than if the potential for exposure is restricted to a small group of travelers. For example, in the August 24, 2018, final order adding four diseases to the PRV-eligible list (83 FR 42904), chikungunya and Lassa fever were noted as being principally imported diseases in their limited occurrence in developed countries (as also noted for Chagas disease and neurocysticercosis in the August 2015 final order), rabies prophylaxis was analyzed and estimated at below 0.1 percent per year in the United States, and cryptococcal meningitis was noted as not having prophylaxis recommendations at present even in highly immunocompromised patients. Conversely, in the August 24, 2018, document (83 FR 42896), a significant market for prevention was noted as the reason for not adding pneumocystis pneumonia to the PRV-eligible list.

In the current analysis, FDA has found that a sizeable direct market may exist for products to prevent coccidioidomycosis (*e.g.,* vaccines) in developed nations, depending upon the specific attributes of the product and the recommended population. For this reason, the statutory criterion that there be ''no significant market for prevention or treatment'' of coccidioidomycosis is not met. (21 U.S.C. 360n(a)(3)(S)).

The United States is a high-income economy according to the World Bank list of high-income countries and therefore is considered a developed country for purposes of this order (Ref. 15). The true incidence of coccidioidomycosis in the United States is difficult to establish because reporting is not required in all States, case definitions may vary, and many cases are misdiagnosed or lack confirmatory testing (Refs. 11 and 16). However, up to 150,000 new infections caused by *Coccidioides* spp. are estimated to occur annually in the United States (Ref. 3).

The incidence of reported coccidioidomycosis in the United States has increased in Arizona, California, Nevada, New Mexico, and Utah, from 5.3 per 100,000 population in 1998 to 42.6 per 100,000 in 2011 (Ref. 2). While approximately 96 percent of infections reported in 2017 in the United States occurred in Arizona and California (Ref. 11), coccidioidomycosis is increasingly being recognized outside these regions (Refs. 17 and 18). Proposed reasons for the rise in cases and geographic expansion include changes to the local environment due to climate variation and soil disruption, greater exposure of higher risk individuals, including the immunocompromised, and increased numbers of susceptible individuals living in or traveling to endemic regions (Refs. 9 and 19).

A recent *Morbidity and Mortality Weekly Report* (MMWR) surveillance summary noted fluctuating total numbers of reported U.S. cases in recent years (22,634 in 2011, 8,232 in 2014, 14,364 in 2017), all substantially higher than numbers reported annually in the United States from 1998 to 2000. The MMWR surveillance summary addressed potential factors contributing to such fluctuations, including environmental, population, and reporting changes; noted ''Preliminary modeling estimates of the actual number of cases suggest that the number of symptomatic cases nationwide could be 6 to 14 times higher than the number reported to public health authorities''; and recommended ''[h]ealth care providers should consider a diagnosis of coccidioidomycosis in patients who live or work in or have traveled to areas with known geographic risk for *Coccidioides* and be aware that those areas might be broader than previously recognized'' (Ref. 11).

In the August 2015 final order, FDA used a disease prevalence rate of 0.1 percent of the population in developed countries for aiding in the determination of whether a ''significant market'' may exist for treatment of a disease. For purposes of determining a reasonable indicator for the number of cases of coccidioidomycosis that might be considered for treatment in a given year annual incidence (new cases appearing during a given year) was used by FDA. Based on the 2010 U.S. census population of 308.7 million, and using an estimate of 150,000 total cases per year, the calculated annual incidence rate in the United States would be approximately 0.048 percent (Refs. 4 and 20). These estimates suggest the annual number of persons potentially considered for treatment for coccidioidomycosis in the United States is currently below 0.1 percent of the population. However, these estimates should be considered with due regard to their inherent uncertainty and also in the context of potential development of products for prevention of infection or prevention of disease due to *Coccidioides* spp.

Because of the ongoing environmental exposures and risk factors for severe disease when infection occurs, the market for prevention products such as vaccines could differ substantially from that for treatment of clinically manifest illness. Data to support a market estimate are limited, and discussions of potential vaccine cost-effectiveness have used widely different assumptions regarding annual target population size, from 90,000 (based on targeting birth cohorts in highly endemic regions within California and Arizona) (Ref. 21), to ''many millions'' in a worldwide estimate (Ref. 22).

An annual target population size estimate of 1,035,300 for a coccidioidomycosis vaccine for use in the United States was presented in an Institute of Medicine (IOM) committee report on ''Vaccines for the 21st Century'' commissioned by the National Institutes of Health (NIH), which utilized a quantitative model to provide decision makers with a tool to aid in prioritizing vaccine development (Ref. 23). The committee determined an estimate of annual target population for a coccidioidomycosis vaccine based upon targeting birth cohorts in five States where infections are ''most prominent'' plus persons who migrate into that area. This methodology was used because persons who move into the endemic part of the United States and were not previously vaccinated could be at risk from environmental exposure in the endemic area after their move. The committee report estimates that 90 percent of newborns and 10 percent of persons moving into the targeted areas would receive the vaccine.

Given the purpose of the IOM committee report, the methodology used, and the experts and stakeholders consulted in its development, FDA considers it a reasonable estimate of a potential target population for a licensed coccidioidomycosis vaccine. We acknowledge that there are limitations to any hypothetical estimate of a recommended population for a licensed coccidioidomycosis vaccine, and the true population would depend upon multiple factors that include, but are not limited to: The incidence and/or prevalence of disease, the extent of exposure risks that may not be readily avoidable by means other than vaccination, and the indication, safety profile, efficacy, and durability of the immune response associated with a specific product. However, the IOM analysis predicts a sizeable direct market for products to prevent the disease, and no strong evidence has been found that the potential market has become smaller since the time of the committee report.

A few efforts have been initiated to help facilitate development of products targeting coccidioidomycosis. At present, FDA is aware of funding for

coccidioidomycosis drug development by U.S. government sources, including grants reported as being awarded by FDA and the NIH (Refs. 25 and 26). FDA's Office of Orphan Product Development has accorded orphan product designation to several drugs intended to treat coccidioidomycosis (Ref. 27). FDA added *Coccidioides* species to the ''list of ''qualifying pathogens'' that have the potential to pose a serious threat to human health'' under the Generating Antibiotic Incentives Now title of the Food and Drug Administration Safety and Innovation Act, noting ''[i]t is estimated that up to 60 percent of people living in the endemic areas of southwestern United States have been exposed to the fungus'' (June 5, 2014, 79 FR 32464). *C. immitis* and *C. posadasii* were previously on the HHS list of Select Agents and Toxins but were removed in 2012 based on availability of treatment and a lowered assessment of impact on human health (Ref. 28). Further, *Coccidioides* species are not listed as a high priority threat in the 2017–2018 Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan (Ref. 29).

In summary, based on the analyses outlined above focusing on the estimated vaccination rates of infants born in endemic areas and persons who may be exposed by moving into those areas, FDA has found a significant potential direct market for products for prevention of coccidioidomycosis.

2. Coccidioides spp. Disproportionately Affects Poor and Marginalized Populations

Illnesses caused by *Coccidioides* spp. cause significant morbidity with a disproportionate impact on poor and marginalized populations. In addition to the well-known endemic regions of the United States, cases and outbreaks of coccidioidomycosis have been reported in Mexico, Guatemala, Honduras, Nicaragua, Colombia, Venezuela, Argentina, Brazil, Paraguay, and Bolivia (Ref. 30). With the exception of the United States and Argentina, none of these countries is on the World Bank list of high-income economies, which in the August 2015 final order FDA determined would be used as evidence that the country should be considered a ''developed nation'' for tropical disease determination (Ref. 15). While coccidioidal skin test antigens do not distinguish subclinical infection from symptomatic disease, and recent data from skin test surveys are sparse (Ref. 31), available information indicates that coccidioidomycosis may be as prevalent in parts of Latin America as in parts of the United States (Refs. 30 and 32). Coccidioidin skin test surveys in Mexico some decades ago were reported as demonstrating positivity ranging from 10 percent in Tijuana, to 40 percent in Torreon, to as high as 93 percent in 12 communities in Coahuila (Ref. 30). In Brazil, by one estimate, 7.12 of 1,000 hospital admissions were due to coccidioidomycosis (Ref. 33). Treatment options are more limited in Latin America than in the United States, as lipid formulations of amphotericin have restricted availability due to the high cost (Ref. 34).

In the United States, several racial and ethnic minority groups have been reported to have increased risk of severe disease; genetic, socioeconomic, occupational, and geographic factors have been suggested as potentially contributory factors. Analyses of hospitalizations from 2000 to 2011 and deaths from 2000 to 2013 in California have reported higher rates in African-Americans, Hispanics, and older persons compared to the general population (Refs. 35 and 36). Among immunocompromised or immunosuppressed populations, persons with HIV infection were reported to be strikingly vulnerable during the early years of the HIV pandemic. While effective antiretroviral therapy has decreased the disease burden in individuals with HIV, affected patients lacking access to treatment, or with poorly-controlled disease, are at higher risk for severe or disseminated disease (Ref. 37).

While adults over the age of 60 have the highest incidence of coccidioidomycosis (Ref. 38), children under the age of 17 and their caretakers bear a substantial burden of the disease in endemic regions, experiencing delays in diagnosis, prolonged symptoms, hospitalizations, and missed school and work (Ref. 39). In California, for example, during a period when reported cases and hospitalizations in the general population increased 4.5-fold and 2.7-fold, respectively, cases and hospitalizations in children increased almost 6-fold (Ref. 40).

Prison inmates in endemic regions are at particularly high risk of symptomatic disease. One study in California found that the risk of primary disease was highest in prisoners over the age of 40 and in non-white ethnic groups (Ref. 41). A significant increase in coccidioidomycosis that was observed in two California prisons led to a court ruling excluding inmates from incarceration at those locations if they were in risk groups identified by the American Thoracic Society for high risk of severe coccidioidomycosis (Ref. 42).

Coccidioidomycosis is not currently designated by WHO as a Neglected Tropical Disease and no data were found on Disability-Adjusted Life Years distinguishing the burden attributable to coccidioidomycoses in developing versus developed countries. However, patients with coccidioidomycosis often experience prolonged symptoms, delays in diagnosis, and unnecessary antibacterial therapy (Ref. 43). Due to greater barriers to medical care for diagnosis and treatment, poor and marginalized patents in both developing and developed countries experience a significant burden of disease. Resolution of symptoms may take months, thus resulting in significant impairment of activities of daily living and loss of productivity (Ref. 44).

The above information demonstrates it is reasonable to conclude that coccidioidomycosis disproportionately affects poor and marginalized populations.

B. FDA Determination

Given the factors described above, FDA has determined that coccidioidomycoses meets the statutory criteria of ''disproportionately affects poor and marginalized populations,'' but it does not meet the criteria of ''no significant market in developed nations'' due to the potentially significant direct market for products to prevent the disease. Therefore, FDA declines to designate coccidioidomycosis as an addition to the tropical disease list under section 524 of the FD&C Act.

III. Process for Requesting Additional Diseases To Be Added to the List

FDA's current determination regarding coccidioidomycoses does not prevent interested persons from requesting its consideration in the future. To facilitate the consideration of future additions to the list, FDA established a public docket (see *https://www.regulations.gov,* Docket No. FDA–2008–N–0567) through which interested persons may submit requests for additional diseases to be added to the list. Such requests should be accompanied by information to document that the disease meets the criteria set forth in section 524(a)(3)(S) of the FD&C Act. FDA will periodically review these requests, and, when appropriate, expand the list. For further information, see FDA's Tropical Disease Priority Review Voucher Program web page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.*

IV. Paperwork Reduction Act

This notice reiterates the ''open'' status of the previously established public docket through which interested persons may submit requests for additional diseases to be added to the list of tropical diseases that FDA has found to meet the criteria in section 524(a)(3)(S) of the FD&C Act. Such a request for information is exempt from Office of Management and Budget review under 5 CFR 1320.3(h)(4) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Specifically, ''[f]acts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof'' are exempt, ''provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the full consideration of the comment.''

V. References

The following references marked with an asterisk (*) have been placed on display at the Dockets Management Staff (see **ADDRESSES**). They may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and 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 but is not responsible for any subsequent changes to the websites after this document publishes in the **Federal Register**.

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Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1997–D–0444]

Special Considerations, Incentives, and Programs To Support the Approval of New Animal Drugs for Minor Uses and for Minor Species; 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 draft guidance for industry (GFI) #61 entitled ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' This draft guidance is intended to assist those interested in pursuing FDA approval of new animal drugs intended for minor uses in major species or for use in minor species (MUMS drugs). It outlines the basic statutory and regulatory requirements and special considerations for these approvals, and describes the incentives available to encourage the development of MUMS drugs.

DATES: Submit either electronic or written comments on the draft guidance by November 12, 2020 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–1997–D–0444 for ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Margaret Oeller, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0566, *margaret.oeller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #61 entitled ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' This draft guidance replaces final GFI #61, issued in April 1999 (with a minor update in May 2008) entitled ''FDA Approval of New Animal Drugs for Minor Uses and for Minor Species.'' This draft guidance, when finalized, should assist those interested in pursuing FDA approval of MUMS drugs. It outlines the basic statutory and regulatory requirements and special considerations for these approvals, and describes the incentives available to encourage the development of MUMS drugs.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on approval MUMS 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

FDA tentatively concludes that this draft guidance contains no 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 draft 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 part 511 have been approved under OMB control number 0910–0117; in 21 CFR part 514 have been approved under OMB control numbers 0910–0032 and 0910–0284; and in 21 CFR part 516 have been approved under OMB control numbers 0910–0605 and 0910–0620.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15203 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1980–N–0038 (formerly 80N–0012)]

Vioform-Hydrocortisone Cream, Ointment, and Lotion Containing Iodochlorhydroxyquin and Hydrocortisone; Final Decision on Proposal To Withdraw Approval of New Drug Applications; Opportunity To Affirm Outstanding Appeal

AGENCY: Food and Drug Administration; HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing that the Initial Decision of the Administrative Law Judge (ALJ), to withdraw approval of the new drug application (NDA) for Vioform-Hydrocortisone Cream, Ointment, and Lotion containing Iodochlorhydroxyquin and Hydrocortisone (Vioform), is the final decision of the Commissioner by operation of law. Several parties to the hearing, including the NDA holder and identical, related, or similar (IRS) product manufacturers, and a non-party participant timely filed exceptions to the ALJ's Initial Decision. FDA recently requested that the current owner of the NDA application, the IRS product manufacturers, and the non-party participant that had timely filed exceptions, or their successors-in-interest, affirm within a specific timeframe their interest in pursuing their appeals of the ALJ's Initial Decision. The NDA holder responded within the timeframe and withdrew its appeal. No other appellants that received actual notice of the Agency's request responded within the timeframe. Accordingly, FDA now deems any exceptions filed by appellants that received notice of the Agency's request to be withdrawn. FDA is, however, offering an opportunity to other IRS product manufacturers, or successors-in-interest, that submitted exceptions to the ALJ's Initial Decision and did not receive notice of FDA's request, to affirm their desire to pursue the appeal. The ALJ's Initial Decision is the final decision of the Commissioner by operation of law; however, if FDA receives a valid request to affirm the appeal, as described in this notice, we will withdraw this notice.

DATES: This notice is applicable July 15, 2020. Any affirmation of interest in pursuing an appeal should be submitted to the docket by August 14, 2020.

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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) was amended by the Drug Amendments Act of 1962, and these amendments provided that new drugs could no longer be approved unless both safety and efficacy had been established for them. As amended, the FD&C Act also required FDA to evaluate drugs approved as safe between 1938 and 1962 to determine whether such drugs were effective and to withdraw approval for any NDA where there was not substantial evidence of the drug's effectiveness. The person contesting the withdrawal of the approval had the burden of coming forward with evidence of effectiveness for the drug. FDA's review of these pre-1962 drugs is known as the Drug Efficacy Study Implementation program.

In a document published in the **Federal Register** of June 20, 1972 (37 FR 12171, available at *https://www.govinfo.gov/content/pkg/FR-1972-06-20/pdf/FR-1972-06-20.pdf*), after receiving reports from the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, and other available evidence, FDA classified Vioform as ''possibly effective'' for its labeled indications relating to use in various dermatoses or as anti-infective agents. Thereafter, Ciba Pharmaceutical Co., the NDA holder of Vioform (NDA 10–412) submitted data intended to support the effectiveness of Vioform. In a document published in the **Federal Register** of September 25, 1981 (46 FR 47408, available at *https://www.govinfo.gov/content/pkg/FR-1981-09-25/pdf/FR-1981-09-25.pdf*), the Director of the Bureau of Drugs (now the Center for Drug Evaluation and Research), after reviewing all the data previously submitted, concluded that Vioform lacks substantial evidence of effectiveness for its labeled indications and that the submitted data do not demonstrate that each component of Vioform makes a significant contribution to the claimed effects of the drug. Further, the Director issued a notice of opportunity for hearing on a proposal to withdraw approval of Vioform.

Ciba-Geigy Corporation (Ciba-Geigy) (formerly Ciba Pharmaceutical Co.) and multiple IRS product manufacturers responded to the notice of opportunity for hearing and submitted requests for hearing. By notice published in the **Federal Register** of August 21, 1984 (49 FR 33173, available at *https://www.govinfo.gov/content/pkg/FR-1984-08-21/pdf/FR-1984-08-21.pdf*), the Commissioner granted a hearing. Following the submission of written testimony and documentary evidence, an ALJ, Daniel J. Davidson, conducted a hearing, which concluded on December 4, 1985. He issued his Initial Decision on February 5, 1988. The ALJ found: (1) That the effectiveness of Vioform had not been established by substantial evidence of adequate and well-controlled studies, (2) that the requirements of the combination drug policy had not been met, and (3) that Vioform is a new drug under 21 U.S.C. 321(p). Ciba-Geigy, the IRS product manufacturers, and one non-party participant timely appealed the ALJ's Initial Decision by filing exceptions with the Commissioner under § 12.125 (21 CFR 12.125).

FDA recently sent letters to persons that submitted timely exceptions or that FDA identified as successors-in-interest to parties that submitted timely exceptions. The letters requested that the persons that filed exceptions to the ALJ's Initial Decision, or their successors-in-interest, affirm their intent to pursue their appeals and informed them that, if they did not respond and affirm their desire to pursue their appeal by a specified date, the Office of the Commissioner would conclude that they no longer wish to pursue the appeal of the ALJ's Initial Decision and would proceed as if the appeal has been withdrawn. The Office of the Commissioner received a response from Novartis, the current NDA holder and successor-in-interest to Ciba-Geigy. In its letter, Novartis states that it does not wish to pursue the appeal of the ALJ's Initial Decision. The letter also references a previous request to withdraw the approval of the NDA for Vioform and states that Novartis expects ''the NDA withdrawal in due course.''

The Office of the Commissioner also received a letter from Mr. Edward John Allera (Mr. Allera) on behalf of an unidentified client on October 23, 2017. In that letter, Mr. Allera stated that he represented a client that was in the process of acquiring an interest in an IRS product for which the original manufacturer filed timely exceptions. Mr. Allera stated that he would like to affirm his client's intent to pursue the other manufacturer's appeal of the ALJ's Initial Decision. By letter dated December 21, 2017, Mr. Allera reaffirmed his client's wish to pursue the appeal after acquiring an interest in the IRS product. Mr. Allera's October 2017 letter made clear that, as of the date specified to respond, his client neither had appealed the ALJ's Initial Decision in this proceeding by timely filing exceptions nor was, at that time, a successor-in-interest to a party that filed exceptions. Only parties that submitted timely exceptions or were actual successors-in-interest to parties that submitted timely exceptions could affirm an interest in pursuing the appeal. See § 12.125(a). Given that Mr. Allera's client met neither criterion, Mr. Allera's client had no existing qualifying interest in pursuing the appeal to affirm.

The Office of the Commissioner did not receive a response from any IRS product manufacturers, or their successors-in-interest, that filed timely exceptions to the ALJ's Initial Decision and that received notice of the Agency's request to affirm their interest in pursuing their appeals of the ALJ's Initial Decision. The deadlines for responding to the Agency's requests have now passed. Therefore, the Commissioner now deems the exceptions filed by appellants that received notice of the Agency's requests to be withdrawn.

Despite FDA's efforts, based upon the responses to the recent letters, FDA cannot eliminate the possibility that there might be parties or successors-in-interest that filed timely exceptions but did not receive FDA's letter. FDA is thus providing an opportunity for any such person to affirm its interest in pursuing its appeal. The Agency will only deem effective affirmations from persons that did not receive a letter from FDA and that can establish: (1) That the person is a party or a successor-in-interest to a party that submitted timely exceptions and (2) that the person was a party or a successor-in-interest during the time designated for it to respond to FDA's recent letters. Any affirmation of interest in pursuing an appeal should be submitted to the docket by (see **DATES**). The submission should include documentation verifying that the person is a party or successor-in-interest to a party that submitted timely exceptions and a statement that the person wishes to pursue the appeal of the ALJ's Initial Decision. FDA will withdraw this notice if we receive a timely affirmation of interest and confirm that the person meets the requisite criteria.

II. Conclusion and Order

Given that the exceptions have all been withdrawn or deemed withdrawn, this proceeding is now in the same procedural posture as if no exceptions had ever been filed. When parties do not file exceptions to the ALJ's Initial Decision, and the Commissioner does not file a notice of review, the ALJ's Initial Decision becomes the final decision of the Commissioner (see § 12.120(e) (21 CFR 12.120(e))). FDA will publish a notice in the **Federal Register** when an initial decision

becomes the final decision of the Commissioner without appeal to or review by the Commissioner (see § 12.120(f)). Therefore, the ALJ's Initial Decision is the final decision of the Commissioner effective 90 days after publication of this notice.

Pursuant to the findings in the ALJ's Initial Decision, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)), there is a lack of substantial evidence that Vioform will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling for the treatment of primary fungal infections or secondarily infected dermatoses. Further, Vioform does not meet the combination drug policy in 21 CFR 300.50 and is a ''new drug'' within the meaning of 21 U.S.C. 321(p). Therefore, approval of the NDA for Vioform is withdrawn October 13, 2020. Distribution of products subject to the Initial Decision in interstate commerce without an approved application is prohibited and subject to regulatory action (see, *e.g.,* sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The full text of the ALJ's Initial Decision may be seen at Dockets Management Staff (Ref. 1).

III. Reference

The following reference is on display at 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.*

1. Initial Decision, Docket No. 80N–0012, ''Proposal to Withdraw Approval of the New Drug Application for Vioform-Hydrocortisone Cream, Ointment and Lotion Containing Iodochlorhydroxyquin and Hydrocortisone under the Drug Efficacy Study Implementation Program.''

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15298 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1402]

Biomarkers and Surrogate Endpoints in Clinical Studies To Support Effectiveness of New Animal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #267 entitled ''Biomarkers and Surrogate Endpoints in Clinical Studies Support Effectiveness of New Animal Drugs.'' The draft guidance, if finalized, will describe FDA's current thinking with respect to assisting sponsors in incorporating biomarkers and surrogate endpoints into proposed clinical investigation protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by October 13, 2020 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–2020–D–1402 for ''Biomarkers and Surrogate Endpoints in Clinical Studies to Support Effectiveness of New Animal 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 the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Storey, Center for Veterinary Medicine (HFV–131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0578, *susan.storey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #267 entitled ''Biomarkers and Surrogate Endpoints in Clinical Studies to Support Effectiveness of New Animal Drugs.'' Section 305 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (Pub. L. 115–234), among other things, directed FDA to hold a public meeting for interested parties to discuss innovative animal drug investigation designs and to issue guidance addressing the incorporation of the use of such elements of investigations as complex adaptive and other novel investigation designs, data from foreign countries, real-world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints into proposed clinical investigation protocols and applications for new animal drugs.

In the **Federal Register** of July 9, 2019 (84 FR 32749), FDA's Center for Veterinary Medicine (CVM) published a notice of a public meeting entitled ''Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs'' giving interested persons until August 17, 2019, to comment on the topics discussed at the public meeting and the questions published in the meeting notice (84 FR 32749 at 32750 to 32751).[1] On August 13, 2019, we published a notice announcing the extension of the comment period to September 16, 2019 (84 FR 40071). CVM received numerous comments on the topics discussed at the public meeting and the questions published in the meeting notice and those comments were considered as the draft GFI #267 was developed.

This draft guidance describes how CVM intends to evaluate biomarkers, including surrogate endpoints, when they are incorporated into clinical investigations submitted to CVM to demonstrate substantial evidence of effectiveness for new animal drug applications or a reasonable expectation of effectiveness for applications for conditional approval of a new animal drug. It also provides information about how sponsors may obtain feedback from CVM on technical issues related to the use of biomarkers before the submission of an application.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the current thinking of FDA regarding the use of biomarkers, including surrogate endpoints, to support the effectiveness of new animal 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

FDA tentatively concludes that this draft guidance contains no 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 draft guidance refers to previously approved FDA collections of information found in FDA regulations for new animal drug applications submitted under sections 512(b) (21 U.S.C. 360b(b)) and 571 of the FD&C Act. These collections of information are subject to review by the OMB under the PRA. The collections of information in 21 part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15240 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

[1] *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/public-meeting-incorporating-alternative-approaches-clinical-investigations-new-animal-drugs.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1400]

Use of Real-World Data and Real-World Evidence To Support Effectiveness of New Animal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #266 entitled ''Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs.'' The draft guidance, if finalized, will describe FDA's current thinking with respect to assisting sponsors in incorporating real-world data and real-world evidence (including ongoing surveillance activities, observational studies, and registry data) into proposed clinical investigation protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by October 13, 2020 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–2020–D–1400 for ''Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal 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 the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Storey, Center for Veterinary Medicine (HFV–131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0578, *susan.storey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #266 entitled ''Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs.'' Section 305 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (Pub. L. 115–234), among other things, directed FDA to hold a public meeting for interested parties to discuss innovative animal drug investigation designs and to issue guidance addressing the incorporation of the use of such elements of investigations as complex adaptive and other novel investigation designs, data from foreign countries, real-world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints into proposed clinical investigation protocols and applications for new animal drugs.

In the **Federal Register** of July 9, 2019 (84 FR 32749), FDA's Center for Veterinary Medicine (CVM) published a notice of a public meeting entitled ''Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs'' giving interested persons until August 17, 2019, to comment on the topics discussed at the public meeting and the questions published in the meeting notice (84 FR 32749 at 32750 to 32751). On August 13, 2019, we published a notice announcing the extension of the comment period to September 16, 2019 (84 FR 40071). CVM received numerous comments on the topics discussed at the public meeting and the questions published in the meeting notice and those comments were considered as the draft GFI #266 was developed.

This draft guidance describes how CVM intends to evaluate real-world data and real-world evidence in submissions to CVM to demonstrate substantial evidence of effectiveness for new animal drug applications or a reasonable expectation of effectiveness for applications for conditional approval of a new animal drug. It also provides information about how sponsors may obtain feedback from CVM on technical issues related to the use of real-world data and real-world evidence before the submission of an application.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the current thinking of FDA regarding the use of real-world data and real-world evidence (including ongoing surveillance activities, observational studies, and registry data) in submissions to CVM to support the effectiveness of new animal 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

FDA tentatively concludes that this draft guidance contains no 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 draft guidance refers to previously approved FDA collections of information found in FDA regulations for new animal drug applications submitted under section 512(b) (21 U.S.C. 360b(b)) and 571 (21 U.S.C. 360ccc–1) of the FD&C Act. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR

part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15243 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1984–N–0259 (formerly 84N–0167)]

Vasodilan Injection and Tablets Containing Isoxsuprine Hydrochloride; Final Decision on Proposal To Withdraw Approval of New Drug Application; Availability of Final Decision

AGENCY: Food and Drug Administration; Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing that the Initial Decision of the Administrative Law Judge (ALJ), that Vasodilan containing Isoxsuprine Hydrochloride had not been shown to be supported by substantial evidence consisting of adequate and well-controlled studies to be effective for treating symptoms relating to senile dementia of the Alzheimer type (SDAT) and multiple infarct dementia and peripheral vascular disease, is the final decision of the Commissioner of Food and Drugs (the Commissioner).

DATES: This notice is applicable July 15, 2020.

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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION: Several parties to the hearing, including the new drug application (NDA) holder and identical, related, or similar (IRS) product manufacturers, filed exceptions to the ALJ's Initial Decision. FDA recently requested that the current owner of the NDA and successors-in-interest to IRS product manufacturers who submitted timely exceptions to the ALJ's Initial Decision affirm, within a specific timeframe, their interest in pursuing their appeals of the ALJ's Initial Decision. FDA did not receive any responses within the specified timeframe. Accordingly, FDA now deems those exceptions as withdrawn. Consequently, the proceeding is in the same procedural position as if no exceptions to the ALJ's Initial Decision had been filed. Therefore, the ALJ's Initial Decision has become the final decision of the Commissioner by operation of law.

I. Background

In 1962, the Federal Food, Drug, and Cosmetic Act (FD&C Act) was amended by the Drug Amendments Act of 1962, and these amendments provided that new drugs could no longer be approved unless both safety and efficacy had been established for them. As amended, the FD&C Act also required FDA to evaluate drugs approved as safe between 1938 and 1962 to determine whether such drugs were effective and to withdraw approval for any NDA where there was not substantial evidence of the drug's effectiveness. The person contesting the withdrawal of the approval had the burden of coming forward with evidence of effectiveness for the drug. FDA's review of these pre-1962 drugs is known as the Drug Efficacy Study Implementation program.

In a notice published in the **Federal Register** of July 11, 1972 (37 FR 13565, available at *https://www.govinfo.gov/content/pkg/FR-1972-07-11/pdf/FR-1972-07-11.pdf*), after receiving reports from the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, FDA stated that Vasodilan Injection and Tablets containing Isoxsuprine Hydrochloride lacked substantial evidence of effectiveness for several indications. In a notice published in the **Federal Register** of May 25, 1979 (44 FR 30443, available at *https://www.govinfo.gov/content/pkg/FR-1979-05-25/pdf/FR-1979-05-25.pdf*), the Director of the Bureau of Drugs (now the Center for Drug Evaluation and Research), after reviewing all the data previously submitted, concluded that Vasodilan lacks substantial evidence of effectiveness for its labeled indications, and proposed to withdraw approval of the NDA and issued a notice of opportunity for hearing on a proposal to withdraw approval of Vasodilan.

Mead Johnson, the NDA holder of Vasodilan (NDA 11–832) submitted data intended to support the effectiveness of Vasodilan for other indications, including: (1) Relief of symptoms associated with SDAT and/or multiple infarct dementia; (2) relief of symptoms associated with peripheral vascular disease of arteriosclerosis obliterans, thromboangiitis obliterans, and Raynaund's disease; and (3) relief of symptoms of uterine motility, including premature labor, dysmenorrhea, and threatened abortion.

Mead Johnson and multiple IRS product manufacturers responded to the notice of opportunity for a hearing and submitted requests for a hearing. By notice published in the **Federal Register** on September 28, 1984 (49 FR 38363, available at *https://www.govinfo.gov/content/pkg/FR-1984-09-28/pdf/FR-1984-09-28.pdf*), the Commissioner granted a hearing; however, the Commissioner only granted a hearing concerning the use of Vasodilan in treating symptoms related to: (1) SDAT or multiple infarct dementia and (2) peripheral vascular disease. Although Mead Johnson requested a hearing on the issue of Vasodilan's effectiveness in relieving symptoms of uterine motility, including premature labor, dysmenorrhea, and threatened abortion, Mead Johnson later abandoned this indication and consented to withdrawal of Vasodilan's approval for it (see id.). Following the submission of written testimony and documentary evidence, an ALJ, Daniel J. Davidson, conducted a hearing and issued his Initial Decision on August 20, 1986. The ALJ found that the effectiveness of Vasodilan had not been shown to be supported by substantial evidence and, as a result, ordered that the approval of the NDA be withdrawn. Mead Johnson and certain IRS product manufacturers timely appealed the ALJ's Initial Decision by filing exceptions with the Commissioner under 21 CFR 12.125.

Separately, by notice published in the **Federal Register** of February 11, 2009 (74 FR 6896), FDA withdrew approval of Vasodilan. The current NDA holder and successor to Mead Johnson, Apothecon, c/o Bristol-Myers Squibb Co. (BMS), had requested that FDA withdraw approval of the application because the drug product was no longer marketed; additionally, BMS waived its opportunity for a hearing on the withdrawal.

On November 9, 2017, FDA sent letters to BMS and the successors-in-

interest to the IRS product manufacturers who submitted timely exceptions, to determine whether the companies remained interested in pursuing their appeals of the ALJ's Initial Decision. FDA informed the companies that, if they did not respond and affirm their desire to pursue their appeals by January 8, 2018, the Office of the Commissioner would conclude that the companies no longer wish to pursue the appeal of the ALJ's Initial Decision and will proceed as if the appeals have been withdrawn. The Office of the Commissioner did not receive a response from any of the companies by the given date; therefore, the Commissioner now deems the exceptions withdrawn.

II. Conclusion and Order

Given that the exceptions have been deemed withdrawn, this proceeding is now in the same procedural posture as if no exceptions had ever been filed. When parties do not file exceptions to the ALJ's Initial Decision, and the Commissioner does not file a notice of review, the ALJ's Initial Decision becomes the final decision of the Commissioner (see 21 CFR 12.120(e)). FDA will publish a notice in the **Federal Register** when an initial decision becomes the final decision of the Commissioner without appeal to or review by the Commissioner (see 21 CFR 12.120(f)).

Pursuant to the findings in the ALJ's Initial Decision, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)), there is a lack of substantial evidence that Vasodilan will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling for: (1) SDAT or multiple infarct dementia and (2) peripheral vascular disease. Distribution of products subject to the Initial Decision in interstate commerce without an approved application is prohibited and subject to regulatory action (see, *e.g.,* sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The full text of the ALJ's Initial Decision may be seen at Dockets Management Staff (see **ADDRESSES**).

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15248 Filed 7–14–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0567]

Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes the Food and Drug Administration (FDA or Agency) to award priority review vouchers (PRVs) to tropical disease product applicants when the applications meet certain criteria. The FD&C Act lists the diseases that are considered tropical diseases for purposes of obtaining PRVs and provides for Agency expansion of that list to include other diseases that satisfy the definition of ''tropical diseases'' eligible for PRVs as set forth in the FD&C Act. The Agency has determined that two foodborne trematode infections, opisthorchiasis and paragonimiasis, satisfy this definition, and is therefore adding them to the list of designated tropical diseases whose product applications may result in the award of PRVs. Sponsors submitting certain drug or biological product applications for the prevention or treatment of opisthorchiasis or paragonimiasis infections may be eligible to receive a PRV if such applications are approved by FDA.

DATES: This order is issued on July 15, 2020.

ADDRESSES: Submit electronic comments on additional diseases suggested for designation to *https://www.regulations.gov.* Submit written comments on additional diseases suggested for designation to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1300, *Katherine.Schumann@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:

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I. Background: Priority Review Voucher Program

Section 524 of the FD&C Act (21 U.S.C. 360n), which was added by section 1102 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), uses a PRV incentive to encourage the development of new drugs, including biological products, for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. To be eligible to receive a tropical disease PRV, a drug must be for prevention or treatment of a ''tropical disease'' as listed under section 524(a)(3) of the FD&C Act. This list can be expanded by the Agency under section 524(a)(3)(S) of the FD&C Act, which authorizes FDA to designate by order ''[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations'' as an addition to the list of tropical diseases, approved drug applications for which may be eligible to receive a PRV. Further information about the tropical disease PRV program can be found in the October 6, 2016 (81 FR 69537), guidance for industry ''Tropical Disease Priority Review Vouchers,'' available at *https://www.fda.gov/media/72569/download.*

On August 20, 2015, FDA published a final order (80 FR 50559) (August 2015 final order) designating Chagas disease and neurocysticercosis as additions to the list of tropical diseases under section 524 of the FD&C Act. The August 2015 final order also sets forth FDA's interpretation of the statutory criteria for tropical disease designation and expands the list of tropical diseases under section 524(a)(3)(R) of the FD&C Act (redesignated as section 524(a)(3)(S) of the FD&C Act). Additions by order to the statutory list of PRV-eligible tropical diseases published in the **Federal Register** can be accessed at *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm534162.htm.*

In this document, FDA has applied its August 2015 final order criteria to analyze whether the foodborne

trematode infections opisthorchiasis and paragonimiasis meet the statutory criteria for addition to the tropical diseases list under section 524 of the FD&C Act.

II. Diseases Being Designated

FDA has considered all diseases submitted to the public docket (FDA–2008–N–0567) between June 20, 2018, and November 21, 2018, as potential additions to the list of tropical diseases under section 524 of the FD&C Act, pursuant to the docket review process explained on the Agency's web page at *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm534162.htm.* Based on an assessment using the criteria from its August 2015 final order, FDA has determined that the following additional diseases will be designated as additions to the list of tropical diseases for purposes of the tropical disease PRV program under section 524 of the FD&C Act:

- Opisthorchiasis
- Paragonimiasis

The four primary foodborne trematode infections identified by the World Health Organization (WHO) include these two infections, as well as fascioliasis, which was included in the original statutory list of tropical diseases under section 524(a)(3) of the FD&C Act, and clonorchiasis, which FDA has determined does not at this time meet the requirements to be designated as an addition to the list of tropical diseases, approved drug applications for which may be eligible for a PRV under section 524 of the FD&C Act (see FDA's ''Notice of Decision Not to Designate Clonorchiasis as an Addition to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act,'' published elsewhere in this issue of the **Federal Register**).

Foodborne trematode infections are caused by parasitic trematodes, commonly known as *flukes.* Trematode infections are naturally transmissible from vertebrate animals to people and back. People become infected through the consumption of raw or undercooked food (*e.g.,* fish, crustaceans, and vegetables), which harbor the minute larval stages of the parasites.

FDA's rationale for adding these diseases to the list is discussed in the analyses that follow.

A. Opisthorchiasis

Opisthorchiasis is caused by the trematodes *Opisthorchis viverrini* or *O. felineus,* acquired by the consumption of raw or undercooked fish (Ref. 1). The natural final hosts of these *O. viverrini* or *O. felineus* flukes are cats and other fish-eating carnivores (Ref. 1). *O. viverrini* flukes are reported in Thailand, Laos, Cambodia, and Vietnam while *O. felineus* flukes are reported in Italy, Germany, Belarus, Russia, Kazakhstan, and Ukraine (Ref. 2).

The final location of adult *O. viverrini* and *O. felineus* is the smaller bile ducts of the liver (Ref. 3). The symptoms caused by opisthorchiasis are related to inflammation and fibrosis of the tissues adjacent to bile ducts. While the majority of infected individuals are asymptomatic, patients may develop cholangitis, intrahepatic calculi, or cholangiohepatitis. Chronic infection is also associated with the development of cholangiocarcinoma, a severe and fatal form of bile duct cancer, and *O. viverrini* are recognized by the International Agency for Research on Cancer as Group 1, which means that the agent is classified as carcinogenic to humans (Refs. 4 and 5).

There is one FDA-approved treatment for opisthorchiasis, praziquantel, approved in 1982 and indicated for the treatment of infections due to all species of schistosoma and infections due to the liver flukes *Clonorchis sinensis* and *O. viverrini* (Ref. 6).

1. No Significant Market in Developed Nations

No significant market exists for the treatment or prevention of opisthorchiasis in developed nations. As stated above, opisthorchiasis occurs as a result of *O. viverrini* and *O. felineus* (Ref. 7). *O. viverrini* have been reported in Thailand, Laos, Cambodia, and Vietnam. *O. felineus* have been reported in Italy, Germany, Belarus, Russia, Kazakhstan, and Ukraine (Ref. 7). Since *O. viverrini* and *O. felineus* have a limited geographic range, infections in other countries only occur from movement of infected persons. *O. viverrini* and *O. felineus* flukes have a life span of 25 to 30 years, meaning that opisthorchiasis may persist long after a patient is initially infected, however, as described below, these numbers are low in developed countries.

Thailand, Laos, Cambodia, Vietnam, Belarus, Russia, Kazakhstan, and Ukraine are not on the World Bank list of high-income economies, which, as described in FDA's August 2015 final order, will be used as evidence that the country should be considered a ''developed nation'' for determination of additions to the PRV-eligible tropical diseases list under section 524 of the FD&C Act (Ref. 8). Germany, Greece, and Italy, however, are on the World Bank list of high-income economies, and therefore are considered to be developed nations for the purposes of this order (Ref. 8).

In developed countries where *O. viverrini* and *O. felineus* are found, the prevalence of opisthorchiasis is very low. There have only been approximately five cases of human infections of *O. felineus* reported in Germany since the 1980s, and two in Greece in the late 1990s and early 2000s (though one of those infections may have originated elsewhere) (Ref. 9). Italy has seen an increase in reported human infections due to the increased consumption of marinated fillets of raw tench (*Tinca tinca*), infected with *O. felineus* (Ref. 9). However, even with this rise in infection rates, the total number of reported opisthorchiasis cases in Italy was only 211 from 2003 to 2011 (Ref. 9). As described in the August 2015 final order, FDA uses a disease prevalence rate of 0.1 percent of the population of developed countries for aiding in the determination of whether a ''significant market'' may exist for a disease's treatment. In these three high-income countries where *O. viverrini* and *O. felineus* have been reported, the prevalence rates are significantly lower than that which FDA would consider could offer a sufficient market incentive to drive the development of new drug products to prevent or treat opisthorchiasis. Therefore, in developed nations where opisthorchiasis occurs, the prevalence rates of infection are not large enough to create a significant market for treatment.

There is currently no estimate of the number of individuals infected with opisthorchiasis in the United States. The available information concerning opisthorchiasis in the United States suggests that the prevalence of opisthorchiasis is much lower than 0.1 percent of the population. Of the infections that do occur in the United States, foodborne trematode infections occur predominantly in immigrants and travelers to and from endemic regions (Refs. 10 and 11). For example, in a retrospective study in one U.S. travel medicine clinic over 6 years, only 17 cases of *Opisthorchis spp.* and *Clonorchis spp.* were identified through the review of medical records (Ref. 12). All patients with identified cases were migrants from Laos, Cambodia, Thailand, Vietnam, the former Soviet Union, and Ecuador (Ref. 12).

There is evidence that U.S. military personnel were exposed to *Opisthorchis spp.* and *Clonorchis spp.* during their service in the Vietnam War (Ref. 13). In one study, there was evidence that veterans were likely previously infected, but patients in the study did not have evidence of ongoing infection, given

negative stool exams and negative imaging studies, and therefore would not have ongoing infections requiring treatment at present (Ref. 13).

As illustrated above, opisthorchiasis occurs rarely in developed nations. The market for drugs for opisthorchiasis in developed nations such as the United States would largely be comprised of immigrants and travelers to and from endemic regions and military populations serving in endemic regions. These markets are unlikely to provide sufficient incentive to encourage development of products to treat or prevent opisthorchiasis. At present, FDA is unaware of any significant funding for opisthorchiasis drug development by the U.S government sources, and opisthorchiasis is not among the Centers for Disease Control and Prevention's (CDC) list of potential bioterrorism agents.

2. Opisthorchiasis Disproportionately Affects Poor and Marginalized Populations

Opisthorchiasis disproportionately affects poor and marginalized populations around the world. Within countries where *O. viverrini* or *O. felineus* are reported, opisthorchiasis predominantly occurs in populations living in impoverished settings. For example, in rural northeast Thailand, where the per capita gross domestic product (GDP) is less than $4,000, reported opisthorchiasis prevalence typically exceeds 30 percent of the population (Ref. 14). In contrast, in urban Bangkok, where the per capita GDP is around $15,000, opisthorchiasis prevalence is reported to be less than 5 percent of the population (Refs. 14 and 15). Likewise, in Laos, in the poorer rural southern provinces (poverty rates of 30 to 50 percent), reported opisthorchiasis prevalence is the highest at 20 to 30 percent, whereas in the relatively wealthier urban Vientiane region of Laos (poverty rate less than 20 percent), opisthorchiasis prevalence is reportedly less than 5 percent (Refs. 15 and 16). In Cambodia, a similar trend is noted, where the highest reported prevalence of opisthorchiasis (24 percent) can be found in the rural Kampong Cham and Takéo provinces, where poverty rates exceed 50 percent (Refs. 15 and 17).

Opisthorchiasis is also included in the WHO List of Neglected Tropical Diseases (Ref. 18). The WHO Foodborne Disease Burden Epidemiology Reference Group identified opisthorchiasis as an important cause of disability, with an estimated annual incidence of over 16,315 infections and 1,498 deaths, resulting in a global disability-adjusted life years (DALYs), which is calculated by adding the number of years of life lost to mortality and the number of years lived with disability due to morbidity due to the illness, of 188,346 (Refs. 19 and 20).

Given the above information, FDA concludes that opisthorchiasis disproportionately affects poor and marginalized populations.

3. FDA Determination

Given the factors described above, FDA has determined that opisthorchiasis meets both the statutory criteria of ''no significant market in developed nations'' and ''disproportionately affects poor and marginalized populations.'' Therefore, FDA is designating opisthorchiasis as an addition to the tropical diseases list under section 524 of the FD&C Act.

B. Paragonimiasis

Paragonimiasis is caused by *Paragonimus spp.,* which are trematodes acquired through the consumption of raw or undercooked crustaceans (crabs and crayfish) (Ref. 1). The natural final hosts of *Paragonimus spp.* are cats, dogs, and other crustacean eating carnivores (Ref. 1). *Paragonimus spp.* are reported in China, the Philippines, Japan, Vietnam, the Republic of Korea (South Korea), Taiwan, Thailand, Central and South America, Africa, and there have been rare reports of these flukes being found in the midwestern United States (Ref. 21). The final location in humans of adult *Paragonimus spp.* is in lung tissue (Ref. 1). The symptoms caused by paragonimiasis are chronic cough with blood-stained sputum, chest pain, dyspnea, and fever (Ref. 1). *Paragonimus spp.* can migrate to other parts of the body, *e.g.,* to the brain, where they can cause severe cerebral manifestations (Ref. 1). There are no FDA-approved treatments for paragonimiasis.

1. No Significant Market in Developed Nations

FDA is unaware of any significant market for the treatment or prevention of paragonimiasis in the United States or other developed nations. As stated above, paragonimiasis is caused by *Paragonimus spp.* flukes that have been reported in China, the Philippines, Japan, Vietnam, South Korea, Taiwan, Thailand, Central and South America, Africa, and there have been rare reports of these flukes being found in the midwestern United States. The limited range of *Paragonimus spp.* means infections outside of these endemic countries only occur from the movement of infected persons. From the countries and regions listed above, South Korea, Taiwan, Uruguay, Chile, and Panama all are on the World Bank's list of high-income economies (Ref. 8).

In developed nations where *Paragonimus spp.* are found, the prevalence of paragonimiasis is low, according to the published data obtained by the Agency. For example, in Japan, there were 443 patients who were referred to one academic institution and diagnosed as having paragonimiasis from 2001 to 2012 (Ref. 22). The majority of native Japanese patients with paragonimiasis were residents of one island; while one quarter of the cases occurred in immigrants mostly from China, Thailand, and Korea (Ref. 22). In South Korea, the prevalence of paragonimiasis has precipitously dropped as the country has developed; in the 1960s, at least 2 million people were estimated to be infected with paragonimiasis based on intradermal testing; by the 1990s, the prevalence was reduced to 1 percent of the previous estimate (Ref. 23). In a relatively recent review of medical records at another large referral medical center in Seoul, South Korea, only 36 patients were diagnosed with pulmonary paragonimiasis over a 10-year period (1994 to 2004). FDA was unable to find published information about the prevalence of paragonimiasis in humans in Uruguay, Chile, Argentina, or Panama (there are rare reports in the midwestern United States). One study reported 16 cases of paragonimiasis acquired in Missouri from 2008 to 2014, which were associated with consumption of raw crayfish (Ref. 24).

The market for drugs for paragonimiasis in most developed nations would largely be comprised of immigrants and travelers from endemic regions. These low prevalence rates in developed countries are unlikely to provide sufficient incentive to encourage development of products to treat or prevent paragonimiasis in developed countries.

2. Paragonimiasis Disproportionately Affects Poor and Marginalized Populations

Paragonimiasis disproportionately affects poor and marginalized populations around the world. The true burden of paragonimiasis is unclear given the population it impacts; under-reporting is likely, particularly in African regions (Refs. 25 and 26). While epidemiologic data for paragonimiasis are scant, transmission of foodborne trematodes within countries is typically restricted to limited areas and reflects behavioral and ecological patterns

which are related to socioeconomic status. This includes people's food habits, methods of food production and preparation, and the distribution of intermediate hosts. For example, food can be contaminated through unhygienic preparation and storage. Furthermore, the consumption of raw fish and crustaceans is a main risk factor for contracting these parasites. The life cycle of the parasites is closely linked with water and sanitation. In populations without access to toilets, or without sewage system infrastructure, unprocessed human and animal fecal waste may be found near water or used as manure or fish feed. This can contaminate drinking water and aquatic vegetables, leading to a continuous cycle of infections.

Paragonimiasis is included in the WHO List of Neglected Tropical Diseases (Ref. 18). The WHO Foodborne Disease Burden Epidemiology Reference Group identified paragonimiasis as an important cause of disability, with an estimated annual incidence rate of 139,238 infections and 250 deaths, resulting in global disability-adjusted life years of 1,048,937 (Ref. 27). Given the above information, FDA has concluded that paragonimiasis disproportionately affects poor and marginalized populations.

3. FDA Determination

Given the factors described above, FDA has determined that paragonimiasis meets both the statutory criteria of ''no significant market in developed nations,'' and ''disproportionately affects poor and marginalized populations.'' Therefore, FDA is designating paragonimiasis as an addition to the tropical diseases list under section 524 of the FD&C Act.

III. Process for Requesting Additional Diseases To Be Added to the List

The purpose of this order is to add diseases to the list of tropical diseases that FDA has found to meet the criteria in section 524(a)(3)(S) of the FD&C Act. By expanding the list with this order, FDA does not mean to preclude the addition of other diseases to this list in the future. Interested persons may submit requests for additional diseases to be added to the list to the public docket established by FDA for this purpose (see *https://www.regulations.gov,* Docket No. FDA–2008–N–0567). Such requests should be accompanied by information to document that the disease meets the criteria set forth in section 524(a)(3)(S) of the FD&C Act. FDA will periodically review these requests, and, when appropriate, expand the list. For further information, visit the Agency's web page at *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm534162.htm.*

IV. Paperwork Reduction Act

This final order reiterates the ''open'' status of the previously established public docket through which interested persons may submit requests for additional diseases to be added to the list of tropical diseases that FDA has found to meet the criteria in section 524(a)(3)(S) of the FD&C Act. Such a request for information is exempt from Office of Management and Budget review under 5 CFR 1320.3(h)(4) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Specifically, facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof are exempt, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the Agency's full consideration of the comment.

V. 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.

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Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15252 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1401]

Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #268 entitled ''Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs.'' The draft guidance, if finalized, will describe FDA's current thinking with respect to assisting sponsors in incorporating complex adaptive and other novel investigation designs into proposed clinical investigation protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by October 13, 2020 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–2020–D–1401 for ''Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal 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 the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Storey, Center for Veterinary Medicine (HFV–131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0578, *susan.storey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #268 entitled ''Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs.'' Section 305 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (Pub. L. 115–234), among other things, directed FDA to hold a public meeting for interested parties to discuss innovative animal drug investigation designs and to issue guidance addressing the incorporation of the use of such elements of investigations as complex adaptive and other novel investigation designs, data from foreign countries, real-world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints into proposed clinical investigation protocols and applications for new animal drugs.

In the **Federal Register** of July 9, 2019 (84 FR 32749), FDA's Center for Veterinary Medicine (CVM) published a notice of a public meeting entitled ''Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs'' giving interested persons until August 17, 2019, to comment on the topics discussed at the public meeting and the questions published in the meeting notice (84 FR 32749 at 32750–32751).[1] On August 13, 2019, we published a notice announcing the extension of the comment period to September 16, 2019 (84 FR 40071). CVM received numerous comments on the topics discussed at the public meeting and the questions published in the meeting notice and those comments were considered as the draft GFI #268 entitled ''Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs'' was developed.

This draft guidance describes principles for designing, conducting, and reporting the results for investigations or studies, including adaptive design features, when they are incorporated into clinical investigations submitted to CVM to demonstrate substantial evidence of effectiveness for new animal drug applications or a reasonable expectation of effectiveness for applications for conditional approval of a new animal drug. It also provides information about how sponsors may obtain feedback from CVM on technical issues related to the use of adaptive and innovative designs before the submission of an application.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the current thinking of FDA regarding the use of complex adaptive and other novel investigation designs to support the effectiveness of new animal 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

FDA tentatively concludes that this draft guidance contains no 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 draft guidance refers to previously approved FDA collections of information found in FDA regulations. These collections of information are subject to review by the OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15239 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

[1] *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/public-meeting-incorporating-alternative-approaches-clinical-investigations-new-animal-drugs.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the July 20, 2020 meeting, an invited panel will present on emergency preparedness for people with dementia with a special focus on the COVID–19 pandemic. The chairs of the subcommittees (Research, Clinical Care, and Long-Term Services and Supports) will present recommendations for adoption by the full Advisory Council.

DATES: The meeting will be held on July 20, 2020 from 1:00 p.m. to 4:30 p.m. EST.

ADDRESSES: The meeting will be virtual, streaming at *http://www.hhs.gov/live.*

Comments: Time is allocated on the agenda to hear public comments from 4:00 p.m. to 4:30 p.m. The time for oral comments will be limited to two (2) minutes per individual. In order to provide a public comment, please register by emailing your name to *napa@hhs.gov* by Thursday, July 16. Registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. *Note:* There may be a 30–45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 3:45 p.m. to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. All participant audio lines will be muted for the duration of the meeting and only

unmuted by the Host at the time of the participant's public comment. Should you have questions during the session email *napa@hhs.gov* and someone will respond to your message as quickly as possible.

In order to ensure accuracy, please submit a written copy of oral comments for the record by emailing *napa@hhs.gov* by Tuesday, July 21. These comments will be shared on the website and reflected in the meeting minutes.

In lieu of oral comments, formal written comments may be submitted for the record by Tuesday, July 21 to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, 202–260–6075, *helen.lamont@hhs.gov.* Note: The meeting will be available to the public live at *www.hhs.gov/live*.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: An invited panel will present on emergency preparedness for people with dementia with a special focus on the COVID–19 pandemic. The chairs of the subcommittees (Research, Clinical Care, and Long-Term Services and Supports) will present recommendations for adoption by the full Advisory Council.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website when available, after the meeting.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: June 16, 2020.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

[FR Doc. 2020–15196 Filed 7–14–20; 8:45 am]

BILLING CODE 4150–05–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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Calcium Channels, GPCRs, and Proteins of Neurodegeneration.

Date: July 28, 2020.

Time: 1:00 p.m. to 5:00 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: Geoffrey G Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; ORIP Training (Training in Veterinary and Comparative Medicine).

Date: August 10, 2020.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John Harold Laity, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–8254, *john.laity@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: July 9, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–15193 Filed 7–14–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting; NIH Human Fetal Tissue Research Ethics Advisory Board—FY2020

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a virtual meeting of the NIH Human Fetal Tissue Research Ethics Advisory Board—FY2020.

The meeting will be open to the public as indicated below. Individuals who need special assistance with virtual attendance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public, as indicated below, 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 and cooperative agreement applications and R&D contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant and cooperative agreement applications and R&D contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIH Human Fetal Tissue Research Ethics Advisory Board—FY2020.

Date: July 31, 2020.

Open: 10:00 a.m.–11:05 a.m.

Agenda: Welcome and Charge to the Ethics Advisory Board; Introduction of Committee Members; Confidentiality and Conflict of Interest Procedures; Meeting Procedures; and Public Comment Period.

Place: Virtual Meeting/Webcast (link for the meeting will be available at *https://osp.od.nih.gov/biotechnology/nih*).

Closed: 11:15 a.m.–4:15 p.m.

Agenda: To make recommendations regarding the ethics of research involving human fetal tissue (HFT) proposed in NIH grant and cooperative agreement applications and R&D contract proposals, as set forth in the NIH Guide Notice NOT–OD–19–128.

Contact Person: Cari Young, ScM, Health Science Policy Analyst, Office of Science Policy, Office of the Director, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838, *SciencePolicy@od.nih.gov*.

''*This notice is being published less than 15 days prior to the meeting due to the unforeseen circumstances of COVID–19 which required the Department's full response and caused a delay in moving this committee and meeting forward.*''

There will be a 20-minute public comment period during the open portion of the meeting. Any member of the public interested in presenting oral comments to the committee, during the public hearing must notify the Contact Person listed on this notice at least 4 days in advance of the meeting to reserve a time slot. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present and oral comments will be limited to two minutes. Both printed and electronic copies are requested for the record. Once all time slots are filled, only written comments will be accepted. Any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The Contact person should receive any written statements no later than 2 days before the meeting. 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 NIH Office of Science Policy's web page: *https://osp.od.nih.gov/biotechnology/nih-human-fetal-tissue-research-ethics-advisory-board/* where an agenda, link to the webcast meeting, and any additional information for the meeting will be posted when available.

Dated: July 10, 2020.

Natasha M. Copeland,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–15241 Filed 7–14–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Eye Council.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council.

Date: August 10, 2020.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Anne E. Schaffner, Ph.D., Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, National Institutes of Health, 6700 B Rockledge Drive, Suite 3400, Bethesda, MD 20892–9300, (301) 451–2020 *aes@nei.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nei.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 9, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–15194 Filed 7–14–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6191–N–01]

Section 8 Housing Choice Vouchers: Implementation of the Housing Choice Voucher Mobility Demonstration

AGENCY: Office of the Assistant Secretary for Public and Indian Housing (PIH), Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: This notice implements the Housing Choice Voucher (HCV) mobility demonstration (''demonstration'') authorized by the Consolidated Appropriations Act, 2019 (''2019 Appropriations Act'') and the Further Consolidated Appropriations Act, 2020 (''2020 Appropriations Act''). Throughout this notice, the 2019 Appropriations Act and 2020 Appropriations Act are referred to together as the ''Appropriations Acts.'' The notice defines Public Housing Agency (PHA) eligibility criteria; establishes the application process, including setting forth the factors HUD will employ in rating and ranking PHA applications; and explains the special rules and requirements applicable to PHAs selected for participation in the demonstration. In addition, the notice identifies the specific waivers and alternative requirements established by the Secretary for the demonstration.

DATES: *Application Due Date:* October 13, 2020.

FOR FURTHER INFORMATION CONTACT: Rebecca Primeaux, Director, Housing Voucher Management and Operations Division, Department of Housing and Urban Development, 451 Seventh Street SW, Room 4214, Washington, DC 20410, telephone number (202) 708–1112. (This is not a toll-free number.) Individuals with hearing or speech impediments may access this number via TTY by calling the Federal Relay during working hours at 800–877–8339. (This is a toll-free number). HUD encourages submission of questions about the demonstration be sent to *HCVmobilitydemonstration@hud.gov.*

SUPPLEMENTARY INFORMATION:

Background

The 2019 Appropriations Act, signed into law on February 15, 2019, made available $25 million to carry out an HCV mobility demonstration (see paragraph (8)) under the heading ''Tenant-Based Rental Assistance''). The 2020 Appropriations Act, signed into law on December 20, 2019, made an additional $25 million available for the demonstration. Of these amounts, up to $10 million is for incremental voucher assistance under Section 8 of the United States Housing Act of 1937 (''the 1937 Act'') (42 U.S.C. 1437f(o)), with the remainder of funding being available for mobility-related services. The 2019 Appropriations Act also makes available $3 million under a separate heading for a research evaluation.

Incremental voucher assistance for the HCV Mobility Demonstration Vouchers (MDVs) and mobility-related services made available under this notice must only be provided to families with children.

The primary purposes of the demonstration are to provide voucher assistance and mobility-related services to families with children to encourage such families to move to lower-poverty areas, to expand their access to opportunity areas, and to evaluate the effectiveness of the strategies pursued under the demonstration.

The 2019 Appropriations Act authorizes the HUD Secretary to waive or specify alternative requirements for certain portions of Section 8 of the 1937 Act in order to facilitate implementation and administration of the Regional Housing Mobility Plans (RHMPs) that are required of the demonstration-participating PHAs.

HUD must submit a report to Congress within five years after the implementation of the demonstration. The demonstration is effective until October 1, 2028. After October 1, 2028, vouchers will no longer be restricted to the purposes under which they were

made available for this demonstration and will become part of a PHA's regular HCV program.

I. Demonstration Program Design

Background

Recent research shows that growing up in neighborhoods with lower levels of poverty improves children's academic achievement and long-term chances of success, and reduces intergenerational poverty.[1] Children who move to low-poverty neighborhoods have also been shown to experience lower rates of hospitalizations, lower hospital spending, and some changes in mental health over the long-term follow-up.[2] Adults given the chance to move to low-poverty neighborhoods experience reductions in extreme obesity and diabetes.[3]

The HCV program offers families with vouchers the opportunity to live in a neighborhood of their choice, including low-poverty, opportunity neighborhoods. Yet, families with HCVs may encounter barriers to using their vouchers in communities with expanded opportunities. Some barriers may be financial, such as saving enough money for a security deposit or maintaining a positive credit score. Other barriers may include inadequate time to find a unit, landlord unwillingness to rent to voucher holders, or limited awareness of neighborhood amenities, such as the location of high-performing schools.

Some PHAs and nonprofits have implemented ''housing mobility programs'' to help reduce barriers for families with vouchers to live in neighborhoods of their choice, including opportunity neighborhoods with high-performing schools, access to jobs, low crime, parks and other amenities.[4] These programs generally include a comprehensive set of services offered to families as well as administrative policy changes. Although there is no universally agreed upon definition of a housing mobility program, these programs often include ''mobility-related services'' such as pre- and post-move supports, family financial assistance (*e.g.* security deposits), landlord outreach, and housing search assistance.[5] They also include administrative policies such as adequate payment standards in opportunity areas and extended voucher search time.

Building on recent research, and evidence from prior and existing housing mobility programs, the Seattle Housing Authority and King County Housing Authority partnered with researchers from Opportunity Insights, to implement and evaluate a housing mobility program they named ''Creating Moves to Opportunity (CMTO).'' The researchers sought to uncover whether families with vouchers faced barriers that prevented them from moving to opportunity areas, or if families ''prefer to live in neighborhoods that offer limited opportunities for upward mobility.''[6]

To answer these questions, the Seattle Housing Authority and King County Housing Authority implemented a randomized controlled trial (RCT) and offered a set of housing mobility-related services to families in a treatment group and business-as-usual services to families in a control group. RCTs are generally understood to be one of the most reliable research methods to study the impacts of a ''treatment,'' by isolating the effects of the treatment by comparing a randomly assigned treatment group against a randomly assigned control group. In an RCT, the treatment group and control group should be as similar as possible to better understand the impacts of a treatment.

Based on the initial report provided by the researchers, the provision of mobility-related services seemingly helped create strong gains in the number of families who moved to opportunity areas.''[7] Researchers and the housing agencies are now expanding their research to see whether a selected set of services, offered at a lower cost, achieve similar results.

HUD recognizes there is compelling evidence to build upon to meet the goals of the demonstration. The initial CMTO results are promising, but more research is needed to understand if these interventions work similarly in other locations and contexts. Through the demonstration, HUD will implement, test, and evaluate whether housing mobility programs intended to increase family choice, expand access to opportunity neighborhoods. HUD will draw upon the program experience, to the extent possible, of the CMTO effort implemented by the Seattle Housing Authority and King County Housing Authority.[6]

Throughout this notice, while HUD uses technical language to describe the format and design of the study, HUD recognizes that research participants being studied are autonomous families and children who are entitled to respect. HUD requires, and PHAs must require, that each family involved in the study gives voluntary and informed consent. HUD and PHAs will protect the privacy of each family involved in the study and will seek informed, voluntary, and written consent for the use or reproduction of any details about a family.

Overview

This demonstration will allow participating PHAs throughout the country to implement housing mobility programs by offering mobility-related services to increase the number of voucher families with children living in opportunity areas. Only families with children may participate in the demonstration. Throughout the notice, HUD uses the term ''families'' or ''families with children'' interchangeably, since only families with children may participate in the demonstration.

[1] Chetty, Hendren, and Katz, ''The Effects of Exposure to Better Neighborhoods on Children: New Evidence from the Moving to Opportunity Experiment,'' *American Economic Review,* April 2016. Chetty and Hendren, ''The Effects of Neighborhoods on Intergenerational Mobility I: Childhood Exposure Effects and II: County Level-Estimates,'' *Quarterly Journal of Economics,* 2018.

[2] Pollack, Blackford, Du, et al. ''Association of Receipt of a Housing Voucher With Subsequent Hospital Utilization and Spending,'' *JAMA.* 322(21):2115–2124. doi:10.1001/jama.2019.17432, 2019. Kessler, Duncan, Gennetian, et al. ''Associations of housing mobility interventions for children in high-poverty neighborhoods with subsequent mental disorders during adolescence,'' *JAMA;* 311(9):937–948. doi:10.1001/jama.2014. 607, 2014, retracted and replaced June 17, 2016.

[3] Ludwig, Sanbonmatsu, Gennetian, et al. ''Neighborhoods, obesity, and diabetes—a randomized social experiment,'' *New England Journal of Medicine;* 365(16):1509–1519. doi:10.1056/NEJMsa1103216, 2011.

[4] The Moving to Opportunity (MTO) experiment is among the most well-known housing mobility interventions. MTO was authorized by Congress in 1992 and made use of HCVs, in combination with housing search and counseling services, to assist low-income families to move from some of America's most distressed urban neighborhoods to lower-poverty communities. In addition to the MTO experiment, large housing mobility programs have been implemented in Chicago, Dallas, and Baltimore, among other locations.

[5] There is no universally agreed upon definition for opportunity area. Some definitions focus exclusively on poverty, while others may look at public transportation, racial and economic diversity, child-care, health care, and/or a variety of other neighborhood amenities. For the purposes of this demonstration, HUD will use its own definition of opportunity area which is described in Section VIII Application Format, Funding Application Form HUD–52515, Part G, Soundness of Approach, Subpart 5: Proposed Methodology and Opportunity Areas.

[6] Bergman, Chetty, DeLuca, Hendren, Katz, and Palmer, ''Creating Moves to Opportunity: Experimental Evidence on Barriers to Neighborhood Choice,'' August 2019. *https://opportunityinsights.org/wp-content/uploads/2019/08/cmto_paper.pdf.*

[7] Id.

[6] For example, the demonstration will include post-move supports while CMTO does not include them as part of their mobility-related services.

In addition to offering mobility-related services, participating PHAs will work together in their regions to adopt administrative policies that further enable housing mobility, increase landlord participation, and reduce barriers for families to move across PHA jurisdictions through portability.

Although the demonstration is intended to increase housing choice for families in the HCV program, especially in opportunity areas, the demonstration will not require voucher holders to move to designated opportunity areas, limit access to other neighborhoods, or allow for the termination of assistance for lack of participation in mobility-related services.

To be eligible for the demonstration, PHAs must meet eligibility criteria, described in *Section V Application Process,* of this notice. The demonstration includes four statutory categories of eligibility. These are discussed in *Section V Application Process* and *Section VII Application Format.* They are Category A: PHA Partnerships; Category B: Consortia with High-Performing Family Self-Sufficiency (FSS) Program; Category C: Consortia with Small PHA; and Category D: Single Agency. As a result of these eligibility categories, HUD anticipates most applications for the demonstration will come from multiple PHAs within a region submitting one application jointly. References to ''PHAs'' or ''participating PHAs'' or ''PHA sites'' generally mean the successful applicant sites, which may or may not include more than one PHA. When PHAs apply jointly, HUD requires one PHA to be designated the lead PHA. The lead PHA will be awarded the mobility-related service funding. However, all PHAs, whether applying alone or as part of a joint application, may request MDVs.

The demonstration is anticipated to be implemented by PHAs over the course of six years. If selected, PHAs will be required to, among other things:

- Offer and provide a set of agreed upon services and adopt certain administrative policies (described in *Section III Mobility-related Services*);
- Participate in the research evaluation (described in *Section II Research Evaluation*); and
- Recruit and enroll families to participate in the demonstration (described in *Section II Research Evaluation*).

II. Research Evaluation

The Appropriations Acts require HUD to evaluate the effectiveness of the strategies pursued under the demonstration. To meet this requirement, HUD will conduct an independent evaluation to assess the extent to which mobility-related services facilitate moves to opportunity areas, and the length of time families remain in opportunity areas. HUD will develop a final research evaluation within the five years after full implementation of the demonstration. HUD will disseminate any interim findings as required by the statute.

HUD intends to conduct a randomized controlled trial (RCT) at all PHAs participating in the demonstration.[7] Families with children receiving voucher assistance that agree to participate in the demonstration will be randomly assigned to a treatment group that receives mobility-related services or a control group that receives HCV program business-as-usual services already offered by participating PHAs to all HCV applicants and participants.

The demonstration will have two different treatment groups. The first treatment group will receive comprehensive mobility-related services (CMRS). HUD estimates that the CMRS treatment group will be implemented in years one through six of the demonstration, with year one largely being a planning and piloting phase. The second treatment group will receive a subset of the comprehensive housing mobility-related services, which HUD calls selected mobility-related services (SMRS).[8] HUD estimates that the second treatment group, SMRS, will be added in years three through six of the demonstration, with year three largely being a planning and piloting phase for SMRS. Both treatments, CMRS and SMRS, will be offered in years four through six. For a sample timeline, please see Table 3: Potential Minimum Enrollment Schedule at Each PHA Site.

The demonstration will also have a control group. The control group will be recruited and enrolled concurrently with recruitment and enrollment for the treatment groups.

The demonstration will recruit and enroll two different types of families with children for both treatment groups and the control group: Existing voucher holders and new admissions. These are described in further detail in the ''Demonstration Size'' section.

PHAs that participate in the demonstration must agree to implement both the CMRS and SMRS treatments, as well as recruit and enroll both types of families with children. Participating PHAs will work collaboratively with HUD to implement the demonstration, including designing, planning, and piloting the demonstration program; recruiting, enrolling, and randomly assigning families; and, providing mobility-related services.

PHA Responsibilities Related to Research

PHAs participating in the demonstration will have a range of responsibilities related to the research evaluation. These include, but are not limited to, enrolling families to participate, adhering to random assignment protocols, collecting data, and communicating regularly with HUD.

PHAs will be required to enroll a minimum number of families with children to participate in treatment and control groups over the estimated six years of the demonstration. (This is illustrated further in Table 3: ''Potential Minimum Enrollment Schedule at Each PHA Site.) In their application, PHAs will propose the number of families they want to enroll. After selection, HUD will work closely with PHAs to finalize the number of families to be enrolled, based on the final award made to the PHA and the agreed upon budget for mobility-related services. HUD also will work with PHAs to develop a schedule for enrollment. PHAs will not be required to continue to enroll families, if they no longer have enough funding to provide mobility-related services (*e.g.* original mobility-related service cost estimates were too low or other unforeseen circumstances).

By responding to this notice, participating PHAs agree that they will implement random assignment protocols established by HUD. Under these protocols, PHAs will inform families about the demonstration, and ask families with children if they consent to being part of the demonstration. If the family consents, the PHA will randomly assign the family to a treatment or control group. Participation in the demonstration is voluntary and families may decline to participate at any time. PHAs shall not require families to move to an opportunity area or participate in any services in order to retain or obtain a voucher.

In order to evaluate the impact of the demonstration over time, families that consent to participate will agree to: (a) Have their administrative data linked with other administrative datasets and allow their data to be tracked over time; (b) participate in an initial survey; and, (c) be contacted for future surveys. In addition to informed consent, each

[7] See *Section I Demonstration Program Design* for a definition of randomized controlled trial.

[8] See *Section III Mobility-related Services,* for the complete explanation of the term, ''Selected Mobility-Related Services (SMRS).''

family should be given sufficient information to make an informed choice about if, when, and how to participate in each stage of the study process. All applicable informed consent protocols and forms will be developed by HUD.

In addition to the activities described above, PHAs may be required to:

- Administer informed consent to families participating in the demonstration;
- Administer a baseline data collection at time of consent and at other intervals;
- Track services offered, taken up, and the cost of such services on a per-family basis;
- Ensure PHA staff and service providers are available for interviews; and
- Facilitate communication between HUD and families if necessary.

All described activities may or may not be required depending on the final research evaluation design. To help minimize administrative burden on PHA staff, service providers, and families participating in the demonstration, HUD intends to contract with a technical assistance (TA) provider that will support PHA implementation. For example, the TA provider might be tasked with developing a suite of products to be used and customized for providing mobility-related services across selected sites. The TA provider might also help coordinate policies and procedures across selected sites, among other tasks. The provider may offer training and resources for PHAs selected to participate in the demonstration, including around research activities. Finally, PHAs are eligible to receive start-up funding for the demonstration, described further in *Section IV Award Description.*

A summary of the tasks by demonstration year are included in the following table:

TABLE 1—SUMMARY OF KEY IMPLEMENTATION AND EVALUATION TASKS BY DEMONSTRATION YEAR

Demonstration year	Key implementation and evaluation tasks [9]
Year 1	• Planning and piloting of CMRS at PHA sites. • TA contractor assisting PHAs with implementation. • Evaluator finalizes research design and work plan.
Year 2	• CMRS enrollment and services begin at PHA sites. • TA contractor assisting PHAs with implementation. • Evaluator executes research design.
Year 3	• CMRS enrollment and services continue at PHA sites. • TA contractor assisting PHAs with implementation. • Evaluator executes research design. • Evaluator produces rapid-cycle evaluation of CMRS to inform what components of SMRS should be implemented. • Planning and piloting of SMRS at PHA sites.
Year 4	• CMRS enrollment and services continue at PHA sites. • SMRS enrollment and services begin at PHA sites. • TA contractor assisting PHAs with implementation. • Evaluator executes research design. • Demonstration is considered ''fully implemented'' once SMRS enrollment and services begin.
Year 5	• CMRS enrollment and services continue. • SMRS enrollment and services continue. • TA contractor assisting PHAs with implementation. • Evaluator executes research design. • Evaluator produces the first CMRS Process and Impact Evaluation Report to be submitted to Congress after HUD review and approval.
Year 6	• CMRS enrollment and services continue until end of Year 6. • SMRS enrollment and services continue until end of Year 6. • TA contractor assisting PHAs with implementation. • Evaluator executes research design.
Years 7–9	• Evaluator begins drafting final report. • Evaluator continues to track families who moved in Years 1–6. • Evaluator provides HUD final report. • Final report is published.

[9] HUD has developed scopes of services for an evaluation contract and a technical assistance contract based on available funding. Certain components of the demonstration evaluation and technical assistance are subject to funding availability in future fiscal years.

Families Eligible for Demonstration

The Appropriations Acts require that demonstration participants be families with children, which are families with at least one child aged 17 and under. The demonstration will be open to families with children already participating in the HCV program and interested in moving, called ''existing voucher holders'' throughout this notice. The demonstration also will be open to families with children who are new admissions to the HCV program and are selected off the participating PHA waiting lists.[10]

Demonstration Size

Using publicly available data on costs for mobility-related services, HUD estimates that there is enough available mobility-related service funding to provide services to at least 9,500 families.

As long as the participating PHA sites are able to enroll the minimum number of families participating PHAs do not need to administer a specific number of vouchers to be eligible for the demonstration. The total number of families enrolled in the evaluation at each site will vary depending on the total number of awards, and likely will be higher than the minimum number of required participants. For the evaluation to detect the impacts of the CMRS and SMRS treatments, HUD estimated the minimum number of HCV families with children that must be enrolled (sample

[10] See *Section II Research Evaluation, Required HCV Waiting List Preference* for more information about demonstration waiting list requirements.

size) at each participating PHA site. Preliminary calculations indicate that a minimal sample size of 1,950 families with children at each PHA site, across both treatment groups and the control group, is necessary to detect the effects of the treatments.

As described previously, HUD anticipates that the demonstration will be implemented over a six-year period. Over this time frame, HUD requires that each participating PHA site enroll a minimum of 650 families for CMRS, a minimum of 650 families for SMRS, and a minimum of 650 families for the control group (minimum total of 1,950 families). To enroll the minimum number of families, participating PHA sites likely will need to conduct outreach to more than the minimum number of families, since a certain percentage of families are likely to decline enrolling.[11] Although there is limited data on what percentage of families are likely to decline enrolling in the demonstration, HUD estimates more than 10 percent may decline enrollment.[12]

Table 2 shows the minimum number of families each participating PHA site must enroll in the demonstration. PHAs applying together under Category A: PHA Partnerships, Category B: Consortia with High-Performing FSS Program, or Category C: Consortia with Small Agency, do not need to enroll the minimum number of families at each individual participating PHA. They are required to collectively enroll the minimum number of families across participating PHAs. (See *Section VII Application Format* for further information on these categories.)

TABLE 2—MINIMUM REQUIRED ENROLLED FAMILIES AT EACH PHA SITE

Voucher type	CMRS treatment minimum number of families to be enrolled by PHA	SMRS treatment minimum number of families to be enrolled by PHA	Control minimum number of families to be enrolled by PHA	Total
Existing voucher holders	600	600	600	1,800
New admissions	50	50	50	150
Total	650	650	650	1,950

Table 3 shows a potential enrollment schedule for a participating PHA site that only enrolls the minimum number of families. In their applications, PHAs will estimate the number of families they want to enroll. HUD anticipates that some participating PHA sites will propose to enroll more families.

TABLE 3—POTENTIAL MINIMUM ENROLLMENT SCHEDULE AT EACH PHA SITE

	CMRS new enrollment	SMRS new enrollment	Control group new enrollment	Yearly total new enrollment (treatment & control)	Yearly total new treatment (families receiving CMRS or SMRS)
Year 1	Planning and pilot				
Year 2	130	N/A	130	260	130
Year 3	130	Planning and pilot	130	260	130
Year 4	130	216	130	476	346
Year 5	130	217	130	477	347
Year 6	130	217	130	477	347
Total	650	650	650	1,950 (cumulative)	1,300 (cumulative)

Existing Voucher Holders

To meet the minimum enrollment requirements, PHAs will primarily recruit and enroll existing voucher holders to participate in the demonstration.[13] Recruitment and enrollment of existing voucher holders likely will occur at recertification or when a family indicates interest in moving. Once a family with children indicates they are interested in moving, they will be asked if they are interested in participating in the demonstration and given the opportunity to provide informed consent to participate.

Families who consent to participate will be randomly assigned into one of the treatment groups or the control

[11] HUD reminds PHAs when conducting outreach that all materials, notices, and communications must be provided in a manner that is effective for persons with hearing, visual, and other communication-related disabilities consistent with Section 504 of the Rehabilitation Act and HUD's Section 504 regulation, and Titles II or III of the ADA and implementing regulations. Recipients must provide appropriate auxiliary aids and services necessary to ensure effective communication, which includes ensuring that information is provided in appropriate accessible formats as needed, *e.g.,* Braille, audio, large type, assistive listening devices, and sign language interpreters, accessible websites and other electronic communications (See 24 CFR 8.6, 28 CFR 35.160, 28 CFR 36.303). PHAs also must take reasonable steps to ensure meaningful access to their programs and activities to limited English proficient (LEP) individuals. As an aid to recipients, HUD published Final Guidance to Federal Financial Assistance Recipients: Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (LEP Guidance) in the **Federal Register** on January 22, 2007 (72 FR 2732). LEP guidance and LEP information is available here: *https://www.federalregister.gov/documents/2007/01/22/07-217/final-guidance-to-federal-financial-assistance-recipients-regarding-title-vi-prohibition-against.*

[12] Bergman, Chetty, DeLuca, Hendren, Katz, and Palmer, 2019.

[13] In addition to families with children with regular tenant-based vouchers, existing voucher holders includes families with children assisted with project-based vouchers under Section 8(o)13.

group. All families within the same treatment group must be offered the same set of services. Families randomly assigned to the control group will not receive any mobility-related services but will receive HCV program business-as-usual services already offered by participating PHAs for moving families.

New Admissions

The statute authorized up to $10 million for new incremental vouchers, called MDVs. HUD anticipates about 1,000 new MDVs will be made available under this notice. It is required that all MDVs will be used for new admissions for the treatment groups. PHAs applying for the demonstration must request MDVs which will be competitively awarded among multiple PHA awardees.[14] PHAs must agree to make some regular turnover vouchers available for new admissions. HUD estimates that the number of regular turnover vouchers the PHA must make available will be half the number of the MDVs they are awarded (*e.g.* if the PHA is awarded 100 MDVs, they must make 50 regular turnover vouchers available).

HUD will work with PHAs to develop a waiting list selection plan for the demonstration. For the MDV and regular turnover vouchers, families will be selected off the waiting list in accordance with the participating PHA's preferences, as well as a required preference discussed in the next section.

After selection, families will be asked if they are interested in participating in the demonstration and given the opportunity to provide informed consent to participate. The Appropriations Acts require that MDVs be for families with children participating in the demonstration and shall continue to remain available for families with children upon turnover during the period of the demonstration. Therefore, to receive an MDV, a family selected from the waiting list must consent to participate in the demonstration. If the family selected from the waiting list for an MDV does not provide consent to participate in the demonstration, they will be placed back on the waiting list.

If the family consents, they will be randomly assigned into one of the treatment groups or the control group. All families assigned to the same treatment group must be offered the same set of services. Families assigned to the treatment groups will receive an MDV. Families assigned to the control group will receive a turnover voucher. Families randomly assigned to the control group will not receive any mobility-related services but will receive HCV program business-as-usual services already offered by participating PHAs for moving families.

Across all participating PHA sites, approximately 1,500 total new admission families will participate in the demonstration. About 1,000 MDVs will be assigned to one of the treatment groups and about 500 regular turnover vouchers provided by PHAs will be assigned into the control group.

Required HCV Waiting List Preference

As described previously, the Appropriations Acts require that participants in the demonstration must be families with children. Most participants in the demonstration will be existing voucher holders with children.[15] However, some participants in the demonstration will be new admissions to the HCV program. Most PHAs maintain a waiting list for admission into the HCV program. Under program regulations, PHAs may use a system of waiting list preferences for the selection of families admitted to the program.[16]

Section 235(c)(6) of Division G of the 2019 Appropriations Acts also allows for the ''establishment of priority and preferences for participating families, including a preference for families with young children, as such term is defined by the Secretary, based on regional housing needs and priorities.'' Given this authority, HUD is requiring that PHAs establish a waiting list preference, both for MDVs and for the number of regular turnover vouchers PHAs must make available for the demonstration.

For MDVs awarded to participating PHAs, including any subsequent turnover of those vouchers, the PHA must adopt a waiting list preference. The waiting list preference is for families with at least one child aged 13 and under that live in census tracts with a family poverty rate of 30 percent or higher.[17] Families that receive an MDV voucher will be randomly assigned to one of the treatment groups and will receive mobility-related services.

As described previously, PHAs must agree to make available some of their regular turnover vouchers for new admissions to the demonstration. HUD anticipates that PHAs will need to make available about half as many regular turnover vouchers as awarded MDVs for new admissions.

For the regular turnover vouchers provided by PHAs for the demonstration, in order to fulfill elements of the demonstration's statutorily required evaluation design, PHAs must adopt the same preference for families with at least one child, aged 13 and under, who live in a census tract with a family poverty rate of 30 percent or higher. They must apply this limited preference to their regular turnover vouchers until enough families receiving these regular turnover vouchers have been randomly assigned to the control group.[18]

If a PHA does not have enough families on the waiting list that meet the required preference, the PHA will select the next available family with at least one child aged 17 or under from the waiting list. PHAs must have the administrative capacity to implement this preference.

III. Mobility-Related Services

The Appropriations Acts provide funding for mobility-related services to be implemented under the demonstration. PHAs that participate in the demonstration will be required to implement comprehensive mobility-related services (CMRS) and selected mobility-related services (SMRS). HUD will test whether providing mobility-related services to families with children results in moves to opportunity areas compared to those families that are not offered these services. HUD will use a randomized controlled experiment—the gold standard for measuring causal impacts—to evaluate the effectiveness of the demonstration. PHAs participating in the demonstration will propose administrative policies to be adopted. PHAs will also have the option of developing a regional project-based voucher strategy as part of their participation in the demonstration.

Comprehensive Mobility-Related Services

This section describes the components of CMRS likely to be required for implementation at participating PHAs. In order to

[14] See *Section VII Application Format,* Funding Application HUD Form-52515, Part F Need/Explanation of the Problem for more information.

[15] The waiting list is only applicable to applicants for the HCV program. There is no waiting list for existing voucher holders.

[16] 24 CFR 982.207.

[17] The poverty rate for families is available in American Community Survey table S1702. To access the information at the census tract level 5-Year ACS Tabulations must be used. To access the latest available family poverty rate at the census tract level see: *https://data.census.gov/cedsci/table?q=poverty%20rate&hidePreview=false&tid=ACSST5Y2018.S1702&t=Poverty&vintage=2018.*

[18] An example of a limited preference is when a PHA limits the number of families with young children that qualify for the preference to a specific number of families. For information on a limited preference in a different context please see PIH Notice 2013–15.

effectively implement a randomized controlled experiment, all participating PHA sites will be required to implement substantially the same CMRS.

In their applications, PHAs will describe how they intend to implement these services. PHAs also will have the opportunity in their applications to identify whether there are mobility-related services they think may not be successful in their region. After selection, HUD will work with PHAs to finalize the standard set of CMRS to be offered at all demonstration sites.

HUD recognizes that local experiences and circumstances are also important for crafting an effective set of CMRS. PHAs may be allowed to provide additional services beyond the CMRS if the services do not impact the research design.[19] PHAs will identify in their proposals other services they may want to offer as part of the demonstration.

Although HUD hopes to learn what strategies help families access opportunity areas and will closely monitor the number of moves to opportunity areas, participation in mobility-related services will be entirely voluntary. Families may end participation in mobility-related services at any time and it will not affect their status as an applicant or participant in the HCV program.

Based on available research, HUD has identified CMRS that are likely to be successful in helping families move to opportunity areas. These include a range of services, such as pre-move support and housing search assistance, landlord outreach and support, family financial assistance, landlord financial incentives, post-move, and subsequent-move support, which are described in detail below. PHAs will have the flexibility to work with individual families to customize services, provided every family is offered all of the available services.

Pre-Move Services

- Creating customized plans to address individual family barriers to renting a unit in an opportunity area, such as negative credit, lack of credit, or negative rental or utility history.
- Providing information on schools, the opportunity to tour and meet with school staff, educators, and any necessary educational support services, neighborhood amenities, and the short-term and long-term benefits of moving to an opportunity area.

Housing Search Assistance

- Helping an individual family identify and tour available units in opportunity areas, including physically accessible units and features for family members with disabilities.
- Assisting with the completion of rental applications and PHA forms.
- Expediting the PHA leasing process.

Family Financial Assistance

- Creating customized assistance [20] to help remove certain cost barriers to initial lease-up in an opportunity area by providing funds for application fees, move-in fees, and security deposits.

Landlord Recruitment

- Conducting concerted outreach for increased landlord participation in opportunity areas.
- Providing enhanced customer service.
- Conducting expedited inspections.
- Providing financial incentives with mobility-related service funding such as damage mitigation funds, signing bonuses, or vacancy payments which may help encourage more landlords in opportunity areas to participate.[21]

Post-Move Services

- Helping families locate neighborhood resources and amenities and navigate enrolling their children in the local school.
- Conducting regular check-ins, services, and supporting the adjustment to a new neighborhood.
- Providing subsequent move counseling for families who may want to move again after their initial opportunity area move. PHAs will offer some of the same services they provided initially as part of second-move counseling.

Selected Mobility-Related Services (SMRS)

Based on existing research, it is likely that the intensive nature of supports offered through CMRS will result in an increased number of moves to opportunity areas for participating families. However, based on available data, it is unclear whether individual elements or a streamlined version of CMRS would result in an increased number of moves to opportunity areas. Although it is likely CMRS will result in successful moves to opportunity areas, there may be more cost-effective approaches to expanding housing opportunities for families with children. As such, HUD will test whether a selected subset of mobility-related services is effective at helping families move to and remain in opportunity areas.

Participating PHA sites will also implement SMRS while they continue to offer CMRS. The SMRS implemented by each participating PHA will likely be a subset of the services offered through CMRS. HUD will not finalize the SMRS until at least one year of CMRS has been implemented. HUD will work closely with PHAs to identify what components of CMRS seem most promising to test as SMRS. However, PHAs will identify in their applications which subset of CMRS they would most like to implement as SMRS.

In order to effectively implement a randomized controlled trial, at least two PHA demonstration sites will be required to implement substantially the same SMRS. HUD expects to test between two and four different SMRS interventions. Participating PHAs will be required to offer the SMRS and administrative policies to all participating families in the treatment group, although it is expected not all families will choose to take up every service offered.

Administrative Policies

In order to conduct effective research, HUD and PHAs must balance the administrative policy differences inherent in the HCV program and local contexts with the research need to maintain some level of similarity among certain administrative policies across sites. In their applications, PHAs will describe administrative policies they want to implement through this demonstration, or already have implemented, that promote housing mobility.

HUD has identified at least one policy area where standardization will be required to ensure it is possible to evaluate the effectiveness of the demonstration. HUD will require that PHAs participating in the demonstration offer high enough payment standards in opportunity areas to ensure that families have access to rental units in opportunity areas. HUD also will require that PHAs participating in the demonstration offer the same payment standards to families in the treatment and control group. Please see *Section V Application Process,* for further information on payment standards.

HUD will ask for existing or proposed policies such as voucher search times, portability policies, and other similar

[19] For example, a PHA may want to launch an informal peer-to-peer network of families that have moved to opportunity areas. This likely would not be in the CMRS but should not impact the research design and likely could be implemented by the PHA.

[20] After selection, HUD and PHAs will work collaboratively together to establish reasonable limits on family financial assistance to be provided with mobility-related service funding.

[21] After selection, HUD and PHAs will work collaboratively together to establish reasonable limits on landlord incentives to be provided with mobility-related service funding.

policies that promote housing choices and mobility. After selection, HUD will work collaboratively with participating PHA to ensure these and other administrative policies are adequate to help families access opportunity areas and to ensure a level of consistency across participating sites.

PHAs must agree to update their PHA Plans and Administrative Plans to reflect the required HCV waiting list preference and any finalized policy changes, as applicable.

Regional Project-Based Voucher Plan

Due to the limited number of MDVs made available under the demonstration, and the need for all of those MDVs to be part of the randomized controlled trial research evaluation, PHAs may not project-base any awarded MDVs. Families that receive mobility-related services under the demonstration may, however, move to project-based voucher (PBV) units. PHAs are encouraged to inform families of available PBV units in their service areas.

Although MDVs cannot be project-based, PHAs may use up to two percent of their mobility-related services funding to develop a regional project-based voucher plan. PHAs will develop the plan throughout the first three years of the demonstration. The plan, which will be submitted to HUD at the beginning of the fourth year of the demonstration, must include, at a minimum, (1) an analysis of PBV units that are large enough for families with children and are currently in opportunity areas in the region and (2) a strategy for increasing the number of those types of PBV units throughout the region. While drafting their plans, PHAs may want to analyze barriers to increasing the number of family PBV units in opportunity areas and how to overcome those barriers. PHAs will also want to develop a plan, potentially including strategies for providing mobility-related services to families interested in moving to PBV units.

Memorandum of Understanding and Performance Standards Requirements

After selection, HUD will work collaboratively with all participating PHAs to finalize the program and research design that will be implemented at each participating PHA. The program and research design will include the final set of mobility-related services to be implemented as part of the CMRS, administrative polices to promote expanded housing opportunities, a program budget, and an enrollment plan. The program and research design will also include information on how SMRS treatment likely will be developed and implemented. HUD anticipates that these will be decided within six months of selection.

After the program and research design is finalized, HUD will draft a memorandum of understanding (MOU) that outlines roles, responsibilities, the program and research design, services to be offered, and descriptions of administrative policies, among other things. HUD also will draft a performance standards agreement that outlines programmatic goals, recapture and reallocation terms, a budget, and a payment schedule for mobility-related services.

PHAs will have up to 60 days to review the terms of the MOU and performance standards agreement. Although HUD anticipates that all selected PHAs will want to continue forward with implementation of the demonstration, PHAs will have the option to decline execution of either prior to implementation of the demonstration. However, after the MOU and performance standards agreement have been executed, PHAs will not be able to exit the demonstration without HUD's prior authorization.

It is important for PHAs with existing housing mobility programs to understand that it is possible the final CMRS might not reflect their existing program, yet they will be required to implement services as required by the demonstration.

IV. Award Description

Grant funding of up to $50,000,000 is available through this notice. All awards are subject to statutory constraints and the applicable funding restrictions contained in this notice.

Of the total $50,000,000 made available under this notice, up to $10,000,000 of housing assistance payments (HAP) funding will be available for new increments of Housing Choice Voucher mobility demonstration vouchers (MDVs). HAP funding for MDVs will be renewed annually in accordance with HUD's renewal formula guidance.

The remainder of the funding will be available for mobility-related services. These funds will be released to the PHA on an agreed upon budget and schedule that aligns with HUD's cash management procedures.

HUD expects to make approximately 5–10 awards for MDVs and mobility-related services together. HUD expects the minimum award amount, including both MDVs and mobility-related services funding, likely to be no less than $4,000,000 and the maximum award amount likely to be no more than $10,000,000.

For any public housing agency administering voucher assistance under the demonstration that determines that it no longer has an identified need for such assistance upon turnover, such agency shall notify HUD, and HUD shall recapture such assistance from the agency and reallocate it to any other public housing agency or agencies based on need for voucher assistance in connection with the demonstration.

HUD expects to announce awards under this demonstration in December 2020.

Eligible Uses of Funds

Housing Choice Voucher Mobility Demonstration Vouchers HAP and Administrative Fees

Funds awarded for HAP and administrative fees must be used in accordance with the Appropriations Acts and other applicable guidance. For Moving to Work (MTW) PHAs awarded MDV HAP funds and administrative fees under this demonstration, these funds are not eligible for fungibility. MDVs may be administered in accordance with activities in the approved MTW Plan or Supplement unless MTW provisions are inconsistent with the Appropriations Acts or requirements of this notice. In the event of a conflict between approved MTW activities and flexibilities and the Appropriations Acts or notice language, the Appropriations Acts and notice govern.

Mobility-Related Services Funding

Funds awarded must be used to provide eligible mobility-related services for families with children. Mobility-related services funding is not eligible for fungibility under the MTW demonstration. PHAs may use up to five percent of their allocation of mobility-related services funding for start-up costs such as hiring and training new staff or adopting new technology. As noted in *Section III Mobility Related Services* ''Regional Project-based Voucher Plan,'' PHAs may use up to two percent of their allocation of mobility-related services funding to develop a regional project-based voucher plan.

PHA Administrative Fees

PHAs participating in the demonstration may use administrative fees, their administrative fee reserves, and funding from private entities to provide mobility-related services in connection with the demonstration program, including services such as counseling, portability coordination,

landlord outreach, security deposits, and administrative activities associated with establishing and operating regional mobility programs. PHAs are cautioned that CMRS and SMRS must be offered and to consider whether the terms of any private funding agreements would interfere with their ability to meet demonstration requirements when potentially soliciting or receiving funding from private entities.

PHA HAP Funds

PHAs participating in the demonstration may use housing assistance payments (HAP) funds under section 8(o) of the United States Housing Act of 1937 (42 U.S.C. 1437f(o)) for security deposits [22] if necessary, to enable families participating in the treatment group to lease units with vouchers in designated opportunity areas. HUD anticipates that PHAs generally will use mobility-related service funding for security deposits for the demonstration.

Project-Based Vouchers and HCV Homeownership Program

MDVs, and regular turnover vouchers made available by the PHA specifically for the demonstration, may not be used as project-based vouchers (PBVs) or as HCV homeownership program vouchers, due to design constrains of the research evaluation. The research evaluation will measure the mobility-related services families receive and not efforts made by PHAs to secure physical property in opportunity areas. Evaluating the means by which a PHA can secure specific units in opportunity areas requires a different set of research protocols.

Families participating in the demonstration may move to a PBV unit or purchase a home through the HCV homeownership program. Any MDV voucher holder that chooses to move to a project-based unit or purchase a home through the HCV homeownership program must be offered another voucher from the PHA in accordance with the PHA's policies. Given the limited number of MDVs and regular turnover vouchers required to be made available (*i.e.* about 1,500) HUD anticipates this will not be a significant challenge for PHAs over the course of the demonstration.

Recapture and Reallocation of Funds

Funds awarded under this notice may be recaptured and reallocated and units awarded may be reduced if the PHA does not comply with the requirements of the notice, the performance standards agreement, or the MOU that will be executed after award. If HUD finds a PHA in non-compliance of the terms of the notice, performance standards agreement, or the MOU, HUD may recapture any unspent mobility-related service or voucher funds. HUD may also reallocate any mobility-related service dollars or awarded vouchers to the next highest scoring applicant(s) that applied for the demonstration under this notice. For example, should a selected PHA not make efforts to enroll families to participate in the demonstration, HUD would have the authority to recapture mobility-related service funding from the PHA.

Beneficiary Eligibility

Both the vouchers and the services made available under the demonstration shall be for families with children. This means that a family without children may not participate in the demonstration, receive an MDV, or receive mobility-related services under the demonstration.

V. Application Process

General Eligibility Criteria

Only PHAs that already administer HCVs are eligible to apply. Non-profits that administer Mainstream voucher assistance are not eligible to participate in the demonstration. PHAs that fail to meet any of the following eligibility requirements will be deemed ineligible. Applications from ineligible PHAs will not be evaluated.

Statutory Categories of Eligibility

Only certain PHAs, or groups of PHAs, are eligible to participate in the demonstration. To be eligible to participate in the demonstration, a PHA must meet one of four eligibility categories. Further definitions of the eligibility categories and how PHAs demonstrate they fall into an eligibility category are included in *Section VII Application Format.*

Category A PHAs (PHA Partnerships) are agencies that, together, serve areas with high concentrations of voucher holders in poor, low-opportunity neighborhoods and have an adequate number of moderately priced rental units in high-opportunity areas. For the purposes of the notice, ''high-opportunity'' and ''opportunity area'' have the same meaning.[23]

Category B PHAs (Consortia with High-Performing FSS Program) are in planned consortia or partial consortia of PHAs that include at least one agency with a high-performing FSS program.[24]

Category C PHAs (Consortia with Small PHA) are in planned consortia or partial consortia of PHAs that serve jurisdictions within a single region, include one or more small agencies, and will consolidate mobility-focused operations.[25]

A Category D PHA (Single Agency) is a single agency that serves areas with high concentrations of voucher holders in poor, low-opportunity neighborhoods and has an adequate number of moderately priced rental units in high-opportunity areas. In defining this category, HUD is using its statutory authority, included in Section 235(b)(1)(D) in the 2019 Appropriations Act to establish other categories of PHAs that are eligible to participate in the demonstration.[26]

Other Eligibility Requirements

Required preference—The Appropriations Acts allow for the ''establishment and priority and preferences for participating families, including a preference for families with young children, as such term is defined by the Secretary, based on regional housing needs and priorities.'' As such, HUD is requiring PHAs that participate in the demonstration adopt a preference as described in the *Section II Research Evaluation,* ''Required HCV Waiting List Preference.''

This preference is for the purposes of new admission vouchers under this demonstration only. It does not apply to mobility-related services for existing voucher holders.

Payment standards—PHAs must agree to adopt adequate payment standards in opportunity areas. PHAs must agree that payment standards will be finalized in coordination with HUD after selection. PHAs must agree that the same payment standards will be offered to families in the treatment and control groups.

[22] Authorization for PHAs participating in the demonstration to use non-MDV HAP for security deposits was included in the 2019 Appropriations Act. This flexibility is for PHAs participating in the demonstration only.

[23] PHAs may meet these criteria through one of two ways, either: (1) PHAs that are located in Mandatory Small Area Fair Market Rent areas; or (2) PHAs that meet the criteria using data provided by HUD, as described later in the Notice (see *Section VII Application Format,* Funding Application Form HUD–52515, Part K).

[24] PHAs may meet these criteria using definitions established by HUD, as described later in the Notice (see *Section VII Application Format,* Funding Application Form HUD–52515, Part K).

[25] PHAs may meet these criteria using definitions established by HUD, as described later in the Notice (see *Section VII Application Format,* Funding Application Form HUD–52515, Part K).

[26] A PHA may meet these criteria through one of two ways, either: (1) PHAs that are located in Mandatory Small Area Fair Market Rent areas; or (2) PHAs that meet the criteria using data provided by HUD, as described later in the Notice (see *Section VII Application Format,* Funding Application Form HUD–52515, Part K).

Program evaluation—As a condition of receipt of financial assistance under this notice, all participating PHAs will be required to cooperate with HUD, and any contractors affiliated with HUD in implementing and evaluating this demonstration program.

Civil rights—Outstanding civil rights matters must be addressed to HUD's satisfaction prior to grant award, provided that all applicable legal processes have been satisfied.

Program management findings—The PHA must not have any major unresolved program management findings, including but not limited to, from an inspector general's audit, HUD management review, an independent public accountant audit for the PHA's HCV program, or other significant compliance problems that were not resolved or in the process of being resolved prior to the notice's application deadline. Major program management findings, significant program compliance problems, or being in a funding shortfall, are examples of situations that would cast doubt on the capacity of the PHA to effectively administer any new HCV funding in accordance with applicable HUD regulatory or statutory requirements.

Timely submission of application—Applications submitted after the deadline stated within this notice that do not meet the requirements of the grace period policy (described in Section IX: Application Deadlines) will be marked late. Late applications are ineligible and will not be evaluated.

Other circumstances or requirements affecting PHA eligibility—Outstanding delinquent Federal debts; debarments and/or suspensions; pre-selection review of performance; sufficiency of financial management system; false statements; mandatory disclosure requirements; prohibition against lobbying activities; equal participation of faith-based organizations in HUD programs and activities; and program specific requirements affecting eligibility. Detailed information on each requirement is posted on HUD's funding opportunities page: *https://www.hud.gov/program_offices/spm/gmomgmt/grantsinfo/fundingopps.*

To be eligible, PHAs must agree to other requirements. By submitting an application, PHAs agree to the following:

Provide effective communication—All notices and communications must be provided in a manner that is effective for persons with hearing, visual, and other communication-related disabilities consistent with Section 504 of the Rehabilitation Act and HUD's Section 504 regulation, and Titles II or III of the Americans with Disabilities Act (ADA) and implementing regulations. Recipients must provide appropriate auxiliary aids and services necessary to ensure effective communication, which includes ensuring that information is provided in appropriate accessible formats as needed, *e.g.,* Braille, audio, large type, assistive listening devices, and sign language interpreters, accessible websites and other electronic communications (See 24 CFR 8.6; 28 CFR 35.160, 28 CFR 36.303). PHAs also must take reasonable steps to ensure meaningful access to their programs and activities to limited English proficient (LEP) individuals. As an aid to recipients, HUD published *Final Guidance to Federal Financial Assistance Recipients: Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (LEP Guidance)* in the **Federal Register** on January 22, 2007 (72 FR 2732).

Comply with HCV program requirements—HCVs awarded under this notice will be subject to all program requirements, including those at 24 CFR part 982, except for requirements that are specifically waived, which are described in *Section VI Waivers and Alternative Requirements for the Demonstration.* PHAs must comply with alternative requirements.

VI. Waivers and Alternative Requirements for the Demonstration

Section 235(e)(1) of division G of the 2019 Appropriations Act provides the Secretary with the authority to waive or specify alternative requirements for four provisions of Section 8 of the 1937 Act. These waivers or alternative requirements are exceptions to the normal HCV and PBV requirements, and only apply to the demonstration. Participating PHAs may also request programmatic regulatory waivers, as described in *Section VII Application Format.* PHAs will provide programmatic regulatory waiver requests to HUD in their Regional Housing Mobility Plan.

Consistent with the authority in section 235(e)(1), HUD has decided to exercise the discretionary statutory waiver authority for two of the four provisions in the 1937 Act, as discussed immediately below. HUD has also found good cause to use discretionary regulatory waiver authority provided for in 24 CFR 5.110 for one regulatory waiver needed to implement the demonstration.

Lease Term and Mobility Requirements

Section 235(e)(1)(A) of the 2019 Appropriations Act authorizes the Secretary to waive or specify alternative requirements for Sections 8(o)(7)(A) and 8(o)(13)(E)(i) of the 1937 Act and relevant regulatory provisions.

Section 8(o)(7)(A) provides that ''the lease between the tenant and the owner shall be for a term of not less than one year, except that the public housing agency may approve a shorter term for an initial lease between the tenant and the dwelling unit owner if the public housing agency determines that such shorter term would improve housing opportunities for the tenant and if such shorter term is considered to be a prevailing local market practice.'' HUD is waiving this statutory provision because allowing shorter initial lease terms in certain rental markets may help expand the pool of available landlords and rental units in opportunity areas. HUD is also waiving the corresponding program regulations on the ''term of assisted tenancy'' at 24 CFR 982.309(a)(1) and (2). Using this waiver, PHAs have the discretion to approve shorter initial lease terms if they believe shorter terms will expand the pool of available landlords and rental units in opportunity areas.

Section 8(o)(13)(E)(i) states that for the project-based voucher program, ''each low-income family occupying a dwelling unit assisted under the contract may move from the housing at any time after the family has occupied the dwelling unit for 12 months.'' PHAs must offer each such family the opportunity for continued tenant-based rental assistance, consistent with the requirements in Section 8(o)(13)(E)(ii) and 24 CFR 983.261. HUD is not waiving Section 8(o)(13)(E)(i) because it believes the 12-month standard is reasonable and is fully compatible with the demonstration.

Consistency With PHA Plan

Section 235(e)(1)(B) of the 2019 Appropriations Act authorizes the Secretary to waive or specify alternative requirements for Section 8(o)(13)(C)(i) of the 1937 Act.

Section 8(o)(13)(C)(i) states that, for the project-based voucher program, ''a public housing agency may approve a housing assistance payment contract only if the contract is consistent with the public housing agency plan for the agency . . .'' Although vouchers made available under this notice cannot be project-based, as discussed earlier in *Section II Mobility-related Services,* PHAs may use up to two percent of their mobility-related services funding to

develop a regional project-based voucher plan. The plan must include, at a minimum (1) an analysis of PBV units large enough for families with children located in opportunity areas in the region, and (2) a strategy for increasing the number of those types of PBV units in opportunity areas throughout the region.

HUD is waiving this statutory provision to allow PHAs the flexibility to develop a regional project-based voucher plan that is inconsistent with the current PHA plan.

Portability Waiver

Section 235(e)(1)(C) of the 2019 Appropriations Act authorizes the Secretary to waive or specify alternative requirements for Section 8(r)(2) of the 1937 Act which provides that, with respect to portability, ''the PHA having authority with respect to the dwelling unit to which a family moves . . . shall have the responsibility of carrying out the [statutory portability] provisions with respect to the family.''

The geographical areas in which PHAs may administer vouchers is largely governed by state law. HUD is not waiving Section 8(r)(2). The agency believes that there must be compelling reasons for waiving this statutory provision, given that a waiver could result in substantial overriding of state laws in a fundamental area like PHA jurisdiction. Accordingly, HUD does not believe such compelling reasons exist with respect to the demonstration. Rather than waive this statutory provision, HUD is requiring PHAs applying for the demonstration provide information on how they plan to streamline portability policies and procedures across their region.[27] HUD believes PHAs can adequately streamline portability policies and procedures without this statutory waiver.

Section Eight Management Assessment Program Waiver and Alternative Requirement

Under the HCV program, a PHA may receive deconcentration bonus points under the Section Eight Management Assessment Program (SEMAP) if the PHA submits deconcentration data in a HUD-prescribed format, and HUD verifies that the PHA met the requirements for the bonus. For any PHA participating in the demonstration, HUD is waiving 24 CFR 985.3(h), which governs the deconcentration bonus points. Instead, HUD is providing that such a PHA shall receive deconcentration bonus points for the first year after full implementation of the demonstration and for the rest of the years the PHA participates in the demonstration. This provision is not applicable to MTW agencies that do not participate in SEMAP.

Consortia Waivers and Alternative Requirements

Section 235(e)(1) of division G of the 2019 Appropriations Act requires HUD to provide two sets of alternative requirements related to consortia for the purposes of the demonstration. The first set is to allow a consortium that has a single HCV funding contract and the second set is to allow PHAs to enter into a partial consortium to operate all or portions of the Regional Housing Mobility Plan.

In the HCV program, the formation of consortia is governed by the 1937 Act, 42 U.S.C. 1437k and 24 CFR part 943, subpart B. Generally, the statute and regulations provide that two or more PHAs may enter into a consortium agreement and that each PHA will maintain its identity, including its board and PHA code, and its Annual Contributions Contract (ACC) with HUD.

Alternative Requirements for a Single HCV Funding Contract Consortium

In July 2014, HUD issued a proposed rule, ''Streamlining Requirements Applicable to Formation of Consortia by Public Housing Agencies'' in the **Federal Register**.[28] Although the rule has yet to be finalized, for the purposes of PHAs applying as a single HCV funding contract consortium for this demonstration, HUD will waive program regulations at 24 CFR part 943, subpart B, and provide for the use of alternative requirements required by section 235(e)(2) based on the standards in the proposed rule.[29] These alternative requirements are provided in Attachment B of this notice. The proposed rule does not provide for the participation of MTW agencies in a single HCV funding contract consortium and therefore the alternative requirements do not either.

PHAs interested in forming a single HCV funding contract consortium will submit a proposal for implementation as part of their application. A description of how PHAs submit their applications for a single HCV funding contract consortium is in *Section VII Application Format,* Part K.

Alternative Requirements for a Partial Consortium

HUD has considered numerous options for providing alternative requirements for forming partial consortia. After significant analysis, HUD has not been able to develop viable alternative requirements for partial consortia within the constraints of the existing statutory framework at 42 U.S.C. 1437k. There are, in HUD's view, statutory provisions that are not compatible with the establishment of partial consortia. For example, the statute requires that all planning and reporting requirements must be consolidated for PHAs participating in a consortium. It is unclear how PHAs participating in a partial consortium would be able to consolidate all of their planning and reporting requirements. In addition, the Single Audit Act requires audits of non-Federal entities that expend more than $750,000 from all federal sources. This means that each PHA member in a partial consortium that receives more than $750,000 in Federal funds from all sources would require an individual audit and be unable to consolidate all of their planning and reporting as required by 42 U.S.C. 1437k.

Although HUD was unable to determine a set of alternative requirements for partial consortia within the statutory requirements, it may be possible that PHAs interested in applying for the demonstration have an innovative approach to resolving the challenges resulting from the statutory constraints. PHAs interested in participating in partial consortia may submit a proposal for implementing a partial consortium as part of their application. HUD will evaluate each proposal on a case-by-case basis to ensure it meets the statutory requirements and consider any potential regulatory waivers that are statutorily allowable. A description of how PHAs submit their applications for partial consortia is provided in *Section VII Application Format,* Part K.

Effective Dates

As required by section 235(e)(3) of the 2019 Appropriations Act, the waivers and alternative requirements for this demonstration that are listed above will not take effect before the expiration of the 10-day period beginning upon publication of this Notice.

VII. Application Format

There are two types of applicants for the demonstration: (1) PHAs that apply

[27] See *Section VII Application Format,* Funding Application HUD Form–52515, Part G, Regional Housing Mobility Plan.

[28] 79 FR 40019, available at: *https://www.govinfo.gov/content/pkg/FR-2014-07-11/pdf/2014-16151.pdf.*

[29] The proposed rule refers to a single HCV funding contract consortium as a single-ACC consortium.

together under Category A, PHA Partnerships; Category B, Consortia with High-Performing FSS Program; or Category C, Consortia with Small PHA, and (2) a single PHA that applies under Category D, Single Agency.

For the purposes of this section, HUD describes PHAs that apply together—Categories A, B, and C listed above—as joint PHA applicants. Also, for the purposes of this section, HUD describes a PHA that applies alone, Category D, as a single PHA applicant. Joint PHA applicants will submit a single application, which will consist of sections prepared jointly and sections prepared on an individual PHA basis, all of which will be aggregated and submitted together.

Joint PHA and single PHA applicants must submit the application for the demonstration in the format required by HUD by the due date.

The application includes four required forms. These forms, and where they can be downloaded, are listed in Table 4.

Where additional pages are needed to respond to the application, PHAs must comply with the following formatting requirements:

- Use 8½ x 11-inch paper; all margins should be approximately one inch;
- Use at least 10-point font;
- Each page must be numbered;
- Adhere to the page limit requirements of each applicable section. There is no minimum length required for narratives;
- Any pages marked as sub-pages (*e.g.,* with numbers and letters such as 25A, 25B, 25C), will be treated as separate pages;
- If a section is not applicable, indicate ''N/A'';
- No more than one page of text may be placed on one sheet of paper (*i.e.,* you may not shrink pages to get two or more on a page); and
- Shrunken pages, or pages where a minimized/reduced font are used, will be counted as multiple pages.

TABLE 4—REQUIRED FORMS

Form	Submission requirements	Description	Link to form
Funding Application—Form HUD–52515.	For joint PHA applications, Sections A–C and F are required for each individual PHA. Sections D, E and G–L should be completed jointly and only one version should be submitted.	This form will largely be completed through additional attachments.	*https://www.hud.gov/sites/dfiles/PIH/documents/HUD-52515_.pdf.*
	For single PHA applicants, Sections A–L should be completed and submitted.	HUD recommends submitting additional documentation for Parts D–G and K in a document named ''[PHAcode]_attachment 1''; Additional documentation for Part J in a PDF document named ''[PHAcode]_attachment 2'', and additional documentation for Part L in ''[PHAcode]_attachment 3.''	
	Please note that Sections H and I will be blank for all applicants.		
	A sample 52515 and supporting documentation attachments may be found at *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/mobilitydemo*.		
Application for Federal Assistance—Form SF–424 and SF–424B.	For joint PHA applications, all individual PHAs requesting MDVs that are participating in the joint application must submit this form. The lead PHA should include the mobility-related service funding in question 18.	PHAs are encouraged to use additional pages to complete the Form SF–424.	*https://www.hudexchange.info/resource/306/hud-form-sf424/.*
	Single PHA applicants must submit this form.	HUD may contact a PHA to clarify items on this form and items will be treated as a curable deficiency.	
Applicant/Recipient/Disclosure/Update Report—Form HUD–2880.	For joint PHA applications, all individual PHAs participating in a joint application must submit this form.	This is the HUD Applicant Recipient Disclosure form. HUD may contact an applicant to clarify items on this form and items will be treated as a curable deficiency.	*https://files.hudexchange.info/resources/documents/HUD-Form-2880-Applicant-Recipient-Disclosure.pdf.*
	Single PHA applicants must submit this form.		
Disclosure of lobbying activities, if applicable—Form HUD SF–LLL.	For joint PHA applications, all individual PHAs participating in the joint application must submit this form.	This form is only applicable if your agency has used or intends to use non-Federal funds for lobbying activities. HUD may contact an applicant to clarify items on this form and items will be treated as a curable deficiency.	*https://www.hudexchange.info/resource/308/hud-form-sflll/.*
	Single PHA applicants must submit this form.		

Funding Application Form HUD–52515

The Funding Application Form HUD–52515, which is comprised of Parts A–L, is where most of the information required to be submitted to apply for the demonstration is provided. PHAs may provide additional attachments as part of the Funding Application Form HUD–52515. For Parts D–G of Funding Application Form HUD–52515, additional pages submitted by the joint or single PHA applicants may not exceed 43 pages total. HUD will review only the first 43 pages for Parts D–G Funding Application Form HUD–52515, and any responses after 43 pages will not be considered for scoring. Parts K, J and L have no page limit. (Parts H and I will be blank for all applicants.)

HUD recommends submitting additional documentation for Parts D–G and K in a document named ''[PHAcode]_attachment 1''; additional documentation for Part J in a PDF document named ''[PHAcode]_ attachment 2''; and additional documentation for Part L in a document named ''[PHAcode]_attachment 3.'' A sample Funding Application Form HUD–52515 and sample supporting attachments may be found at: *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/mobilitydemo.*

Parts A–C

In Parts A–C, each PHA participating in a joint application, or the single PHA applicant, must provide their name and mailing address, PHA code, and the number of MDVs requested. For example, if five PHAs are part of a joint application, HUD will receive five copies of Funding Application Form HUD–52515 with Parts A–C completed by each individual PHA.

Part D Geographic Area/Jurisdiction (Describe the Area in Which Assisted May Live)

In this part, the joint or single PHA applicant must describe the geographic area in which the PHA, or combination of PHAs, may administer vouchers. Describe how housing agency jurisdictions are created under state law and any implications that may have for participation in the demonstration, particularly as it relates to shared jurisdictions for portability. If needed, one additional page may be added to describe the jurisdiction. Only one Part D will be submitted. For joint PHA applicants it will be submitted as part of the lead PHA's Funding Application Form HUD–52515.

Part E Capacity of the Organization

In this part, the joint or single PHA applicant must submit a narrative description of the capacity and prior experience of the PHAs or PHA. Describe the following:

- Experience managing high-performing voucher programs.
  - PHAs must describe how they effectively manage their program to achieve a high utilization rate, which should include information on how they analyze the waiting list and monitor the success rate to meet both funds and unit utilization goals each year.
  - PHAs must describe how they are providing timely and consistent inspections, providing customer service, adopting technology such as landlord or participant portals, and using mapping software.
- Prior experiences working together with other PHAs on a regional basis through initiatives such as portability, consolidated administrative functions, HCV process or policy alignment, or other collaborations.
- Experience implementing policies and/or programs that promote housing choice for families with children, particularly expanded choices in opportunity areas and any experience implementing a housing mobility program or other mobility-related or similar services, including, but not limited to:
  - Experience adopting and implementing policies to promote moves to opportunity areas, including streamlining portability procedures, increasing voucher search times, providing adequate payment standards in opportunity areas, and housing locator services;
  - Experience conducting outreach to families in high-poverty neighborhoods;
  - Recruiting and retaining landlords, particularly landlords in opportunity areas;
  - Helping voucher families meet landlord screening factors, including but not limited to credit repairs, financial coaching, or security deposit assistance;
  - Implementing and administering Federal, State, local or non-profit grants, programs or activities that demonstrate PHA capacity, which may include, but are not limited to: Special purpose vouchers (*e.g.* HUD-Veterans Affairs Supportive Housing (HUD–VASH), Family Unification, Mainstream vouchers, etc.), the Rental Assistance Demonstration, Low-Income Housing Tax Credit (LIHTC), Community Development Block Grant (CDBG), HOPE VI or Choice Neighborhoods grants; and
  - Participating in research studies, including a randomized controlled trial, research evaluation or demonstrations, such as quantitative or qualitative research, or other experience with data analysis or mapping.
- Data and information on the PHAs' program size to support the number of proposed enrollees for the research evaluation. PHAs will propose the number of enrollees in *Part F Need/Extent of the Problem.* In this Part E, PHAs must submit the program data and information to support the number of enrollees proposed in Part F. PHAs also may submit a narrative on any of these data elements to describe program performance, which may include discussion of relevant program operations and performance experience. Although only one Part E will be submitted for joint PHA applicants, each PHA must provide the following information at an individual PHA-level. The lead PHA will submit all PHA applicants' information in their Funding Application Form HUD–52515. To support the number of proposed enrollees described in *Part F Need/Extent of the Problem,* applicants will likely submit data on the following, but are not limited to these elements only:
  - Number of families with children on waiting list;
  - Number of recertifications completed for families with children between January 1, 2010 and December 31, 2019;
  - Number of families with children currently leased as of December 31, 2019;
  - Number of families with children currently leased in proposed opportunity areas in the PHA's jurisdiction as of December 31, 2019;
  - Voucher program attrition rate for prior three calendar years;
  - New program lease-ups in the regular voucher program over past three calendar years;
  - Program-wide voucher success rate as of December 31, 2019;
  - Utilization rate of regular HCVs as of December 31, 2019 for (1) HAP expenditures compared to available budget authority and (2) units leased compared to authorized voucher levels;
  - Utilization rate of special purpose vouchers as of December 31, 2019 for (1) HAP expenditures compared to available budget authority and (2) units leased compared to authorized voucher levels Average days to lease as of December 31, 2019;
  - Average days from receipt of request from tenancy approval to a passed inspection as of December 31, 2019; and

○ Annual number of inbound and outbound ports in 2019, along with narrative describing the general pattern of portability for the PHA.

This part is limited to eight additional pages.

Part F Need/Extent of the Problem

In this part, joint and single PHA applicants must describe the need for MDVs and request the number of MDVs they would like to be awarded. For joint PHA applicants, all participating PHAs may request MDVs but at least one PHA is required to request MDVs.

The number of MDVs requested must be supported by data showing the number of families with children in the jurisdiction that reside in high-poverty areas. PHAs must show there is adequate need for MDV vouchers which is not being met through other existing programs. Each PHA that requests MDVs must submit the request as part of their individual Funding Application Form HUD–52515.

Using Table 5, joint and single PHA applicants will request the amount of mobility-related services funding needed for the duration of the demonstration which HUD anticipates being six years. Table 6 shows an example of how to complete Table 5 using the minimum required enrolled families at each PHA site included in Table 2. A single PHA applicant, or the lead PHA in a joint application, will submit the requested amount of funds for mobility-related services as part of their Funding Application Form HUD–52515. HUD anticipates the cost per enrollee for CMRS to be $4,000 and for SMRS to be $2,000.

TABLE 5—PROPOSED ENROLLMENT AND FUNDING REQUEST

Voucher type	CMRS			SMRS			Control group	
	Proposed number of enrollees	Cost per enrollee	Funding request	Proposed number of enrollees	Cost per enrollee	Funding request	Proposed number of enrollees	Cost per enrollees
Existing voucher holders ..		$4,000			$2,000			$0
New admissions		4,000			2,000			0
Treatment enrollment and services total funding request.								

PHAs may request an additional 5 percent of their total services funding request for startup costs.
PHAs may request an additional 2 percent of their total services funding request for the regional project-based voucher plan. If the PHA requests startup funding or regional project-based voucher plan funding, please provide the request below.
Total services funding request = Startup costs funding request (5 percent of total services funding request) = Project-based voucher plan funding request (2 percent of total services funding request) = Dollars in this chart are in thousands.

TABLE 6—EXAMPLE PROPOSED ENROLLMENT AND FUNDING REQUEST FOR MINIMUM ENROLLMENT SIZE

[Note: dollars in the following chart are in thousands]

Voucher type	CMRS			SMRS			Control group	
	Proposed number of enrollees	Cost per enrollee	Funding request	Proposed number of enrollees	Cost per enrollee	Funding request	Proposed number of enrollees	Cost per enrollee
Existing voucher holders ..	600	$4	$2,400	600	$2	$1,200	600	$0
New admissions	50	4	200	50	2	100	50	0
Treatment enrollment and services total funding request	650	.....	2,600	650	.....	1,300	650	.....

PHAs may request an additional 5 percent of their total services funding request for startup costs. PHAs may request an additional 2 percent of their total services funding request for the regional project-based voucher plan. If the PHA requests startup funding or regional project-based voucher plan funding, please provide the request below.
Total services funding request = $2,600,000 (CMRS) + $1,300,000 (SMRS) = $3,900,000.
Startup costs funding request (5 percent of total services funding request) = $195,000.
Regional project-based voucher plan funding request (2 percent of total services funding request) = $78,000.

For jurisdictions that include an MTW PHA, HUD requires the joint or single PHA applicant to describe existing efforts to meet the statutory objective of increasing housing choices for low-income families. If the MTW PHA currently operates a housing mobility program, please describe the need for additional funding. If the MTW PHA does not currently operate a housing mobility program, please describe why other efforts to meet the statutory objective have not previously included a housing mobility program.

This part is limited to five additional pages.

Part G Soundness of Approach

The Appropriations Acts identifies the required elements of a Regional Housing Mobility Plan and authorizes the Secretary to establish ''any other requirements.'' In this part, joint and single PHA applicants will submit their Regional Housing Mobility Plan (RHMP). The RHMP is limited to 29 total pages, with each subpart having an individual page limit.

The RHMP must include seven subparts:

- Subpart 1: Participating PHAs
- Subpart 2: Community Partnerships
- Subpart 3: Waivers
- Subpart 4: Approach to Implementing a Housing Mobility Program
- Subpart 5: Proposed Methodology and Opportunity Areas
- Subpart 6: Preferences
- Subpart 7: Other HUD Requirements

Subpart 1. Participating PHAs

In this subpart, joint and single PHA applicants must submit a narrative that addresses the following:

- Goals for participating in the demonstration.
- If the single PHA or any participating PHA in a joint PHA application made a commitment of administrative fees, administrative fee reserves, or other in-kind contributions (*e.g.,* existing space for counseling services) to support costs associated with demonstration, the specific amount of each commitment must be noted. Additional funding commitments are not required, nor will they result in higher rankings in the scoring process.

Importantly, also in this subpart, joint PHA applicants must submit information on the roles of all participating PHAs. Joint PHA applicants must submit a narrative that addresses the following:

- A list of all PHAs that will participate in the demonstration, with the lead PHA clearly identified;
- A governance structure, including an organizational chart and decision-making process; and
- Roles and responsibilities of participating PHAs.

Subpart 1 is limited to four pages. Only one Part G, subpart 1 will be submitted. For joint PHA applicants it will be submitted as part of the lead PHA's Funding Application Form HUD–52515.

Subpart 2. Community Partnerships

In this subpart, as required by the statute, joint or single PHA applicants must identify any community-based organizations, nonprofit organizations, businesses, and other entities that will participate in the demonstration and describe the commitments made by each such entity. Joint and single PHA applicants are not required to enter any community partnerships or leverage outside funds for participation in the demonstration. Regions most in need of mobility-related services may have significant challenges in leveraging funding. Applicants are reminded that they will be required to implement a specific program design for the demonstration. However, applicants are not prohibited from entering community partnerships.

Subpart 2 is limited to two pages. Only one Part G, subpart 2 will be submitted. For joint PHA applicants it will be submitted as part of the lead PHA's Funding Application Form HUD–52515. Any MOUs, agreements, or contracts related to these partnerships may be included in *Part J, Memorandum of Understanding,* and do not count toward this page limit.

Subpart 3. Waivers

In this subpart, joint and single PHA applicants must submit information on the waivers or alternative requirements intended to be exercised for the demonstration program that have been described in *Section VI Waivers and Alternative Requirements for the Demonstration.*

Regulatory waivers for good cause may also be requested, subject to statutory limitations and pursuant to 24 CFR 5.110. This part must identify both types of requested waivers—those identified in the *Section VII Waivers and Alternative Requirements for the Demonstration* and other requested waivers.

PHAs have up to 90 days after notification of award to notify HUD of programmatic regulatory waiver requests necessary to implement the demonstration. PHAs will inform HUD of the waiver requested and provide good cause for why such waivers are needed. PHAs may identify additional programmatic regulatory waivers, so HUD will continue to accept and review good cause programmatic regulatory waivers throughout the demonstration, if necessary.

Subpart 3 is limited to three pages. Only one Part G, subpart 3 will be submitted. For joint PHA applicants it will be submitted as part of the lead PHA's Funding Application Form HUD–52515.

Subpart 4. Approach To Implementing a Housing Mobility Program

In this subpart, joint and single PHA applicants must submit an explanation of their proposed approach for participating in the demonstration and a proposed set of mobility-related services. This response must include a clear implementation plan for the demonstration. The narrative must include, at a minimum, proposed plans for the following:

- Providing mobility-related services to families participating in the demonstration;
- Modifying the Comprehensive Mobility Related Services (CMRS) and proposing the Selected Mobility Related Services (SMRS) to be implemented; [30]
- Recruiting and enrolling at least the minimum number of families to participate in the demonstration;
- Executing the required PHA responsibilities related to the evaluation;
- Monitoring the implementation of the demonstration; and
- Administering the program (in-house or through a hired contractor). The PHA must estimate how many staff the PHA or contractor intends to dedicate to the demonstration. If new PHA staff will be hired, PHAs are encouraged to describe the plan to hire and train qualified staff.
- Adopting administrative policies to support the demonstration. These may include:
  - Adopting high enough payment standards for families to access opportunity areas. If the PHA(s) does not currently use Small Area Fair Market Rent (SAFMR), this section must indicate whether the PHA will opt-in to the use of SAFMRs, or if not, their alternative method of ensuring adequate payment standards in opportunity areas;
  - Extending the voucher search term. The PHA must indicate their policies on voucher search times and the duration such extensions will be granted; and
  - Adopting and aligning policies to make it easier for landlords to participate in the HCV program.

For single agency applicants (Category D), the narrative must also include a description of how families will be able to access a wide range of housing choices in the jurisdiction and across jurisdictional lines, if applicable.

For joint PHA applicants only (Categories A, B, and C), the narrative must also include descriptions of the following:

- How the demonstration, including services and research, will be implemented at multiple PHA sites. This must include the roles and responsibilities of each PHA.
- How the PHAs together will streamline portability procedures to allow families to move across jurisdictional lines more easily, if applicable.

If a joint PHA applicant includes an MTW agency, or if the single PHA applicant is an MTW agency, describe any MTW initiatives that could complicate the research or limit housing mobility (*e.g.* rent reform and restrictions on moves or portability).

Joint and single PHA applicants are encouraged, but not required, to identify the barriers families with children have when using their voucher, particularly in low-poverty, opportunity neighborhoods in the jurisdiction(s). Joint and single PHA applicants are encouraged, but not required, to describe the regulatory and policy environment related to voucher utilization throughout their jurisdictions. Examples include: Any adopted or proposed voucher non-

[30] PHAs are reminded that the final set of CMRS and SMRS will be determined collaboratively between PHAs and HUD after selection.

discrimination laws, inclusionary zoning, prioritization of project-based vouchers and/or LIHTC in opportunity areas, rent control, and landlord mitigation funds.

Subpart 4 is limited to 14 pages. Only one Part G, subpart 4 will be submitted. For joint PHA applicants it will be submitted with the lead PHA's Funding Application Form HUD–52515.

Subpart 5. Proposed Methodology and Opportunity Areas

Paragraph (c)(5) of Section 235 of Title II of the 2019 Appropriations Act states that PHAs must, ''specify the criteria that the public housing agencies would use to identify opportunity areas.'' In this subpart, joint and single PHA applicants must describe their proposed opportunity areas and the methodology. The described methodology must incorporate HUD's minimum criteria and should include the criteria proposed by the PHA(s). For purposes of this demonstration, HUD's minimum criteria for an opportunity area is a Census tract in which the family poverty rate is less than 20 percent. In no case will such areas have a family poverty rate equal to or greater than 20 percent.

Examples of additional criteria that might be proposed by PHAs might include school performance, access to transportation, availability of educational and employment opportunities, and access to essential businesses.

As discussed throughout this notice, HUD is requiring that selected PHAs work together with HUD to identify the specific areas in their jurisdiction to be designated as opportunity areas. PHAs that are selected will have an opportunity for input on the basic criteria and data sources to be used to designate opportunity areas. In this process, PHAs will have the opportunity to discuss their proposed criteria, and the ability to apply local information and knowledge of market conditions.

This structure will allow for a common approach in defining opportunity areas across all demonstration sites, while leaving the specific designations in each jurisdiction up to the agreement between each site and HUD. The final designations of the specific areas will be determined in a collaborative manner.

All PHAs should use the tool located at *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/mobilitydemo* to create a map of their proposed opportunity areas that will be submitted in the application.

Subpart 5 is limited to four pages. Only one Part G, subpart 5 will be submitted. For joint PHA applicants it will be submitted with the lead PHA's Funding Application Form HUD–52515.

Subpart 6. Preferences

Joint and single PHA applicants must certify adoption of the required preference in part L. The required preference is described in the *Section II Research Evaluation,* Required HCV Waiting List Preference. Joint and single PHA applicants respond to Part G, subpart 6 Preferences, in Part L Program Specific Certifications.

No additional information is required for Subpart 6.

Subpart 7. Other HUD Requirements

In this subpart, for joint PHA applicants that will include more than one FSS agency, the PHA must indicate any FSS Action Plan policies that will not align with the demonstration. Also, the PHA must describe how FSS and mobility-related services will be coordinated to avoid the duplication of services and activities.

Subpart 7 is limited to two pages. Only one Part G, subpart 7 will be submitted. For joint PHA applicants it will be submitted with the lead PHA's Funding Application Form HUD–52515.

Part J Memorandum of Understanding

In this part, each PHA participating in a joint PHA application and single PHA applicants must submit a board resolution evidencing the PHA's interest in participating in the demonstration, willingness to comply with all applicable requirements and the evaluation, and the reporting requirements in *Section XII Reporting and Recordkeeping Requirements.*

For PHAs submitting a joint PHA application, this section must include the agreements between participating PHAs, including clear identification of the lead PHA that will receive the mobility-related services funding. HUD must be able to determine from the attached agreements which entity or entities are proposed to provide mobility-related services.

Joint and single PHA applicants may also submit any memoranda of understanding, letters of commitment on agency letterhead, agreements, board resolutions or contracts related to the demonstration in this section.

This part has no page limit. Only one Part J will be submitted. For joint PHA applicants it will be submitted with the lead PHA's Funding Application Form HUD–52515.

Part K Other Information Required

In this part, joint and single PHA applicants must indicate which eligibility category they meet and submit supporting documentation.

This part has no page limit. Only one Part K will be submitted. For joint PHA applicants it will be submitted with the lead PHA's Funding Application Form HUD–52515.

Category A (PHA Partnerships)

PHAs are eligible to participate under Category A if together they serve areas with high concentrations of voucher holders in poor, low-opportunity neighborhoods and have an adequate number of moderately priced rental units in high-opportunity areas.

To qualify under Category A, more than one PHA must be part of the demonstration. In this section, PHAs must identify the PHAs applying together and their combined service area.

PHAs must also document whether they together serve areas with high concentrations of voucher holders in poor, low-opportunity neighborhoods and have an adequate number of moderately priced rental units in high-opportunity areas. PHAs can document this in one of two ways:

(1) Submit documentation that all PHAs applying under this category together are located within a metropolitan area for which HUD has designated the use of mandatory SAFMRs and all of the PHAs that are applying have implemented the SAFMRs.[31] There are 24 designated SAFMR metropolitan areas. A list of these metropolitan areas is provided at the end of this notice, in Attachment A.

(2) Submit documentation showing the joint applicant meets both of the following requirements: [32]

[31] To assist PHAs and simplify the process for applying for the demonstration, HUD has determined that the criteria for designating metropolitan areas for the use of SAFMRs under 24 CFR 888.113(c) meets the statutory definitions required in Category A of this demonstration. The SAFMR definition requires having a percentage of voucher families living in concentrated low-income areas relative to all renters within the area must be at least 25 percent. This meets the statutory definition for the demonstration of ''serving high concentrations of voucher holders in poor, low-opportunity neighborhoods.'' The SAFMR criteria also includes that at least 20 percent of the standard quality rental stock, within the metropolitan FMR area, is in small areas (ZIP codes) where the Small Area FMR is more than 110 percent of the metropolitan FMR. This meets the statutory definition for the demonstration of ''have an adequate number of moderately priced rental units in high-opportunity areas.''

[32] The data sources for these requirements are described in the tools and spreadsheets available at *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/mobilitydemo.*

a. Using a list of PHAs posted by HUD at *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/mobilitydemo* [33] confirm that one or more of the joint applicant PHAs has a percentile score of 60 or above in at least one of two categories:

i. Percentage of voucher holder concentration in poor, low-opportunity neighborhoods compared to all PHAs with 100 more voucher families with children

ii. Number of voucher holders in poor, low-opportunity neighborhoods compared to all PHAs with 100 or more voucher families with children

For the purposes of this demonstration, census tracts that have (i) greater than 25 percent poverty or (ii) designated as a qualified census tract under the LIHTC program are considered ''poor, low-poverty neighborhoods.''

b. Using a data tool of Zip Code Tabulation Areas (ZCTAs) provided by HUD at *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/mobilitydemo* submit a calculation showing that the combined service area of the applicant PHAs have an adequate number of moderately priced rental units in high-opportunity areas. To qualify, at least 20 percent of the standard-quality-rental-stock within the combined service area must be renting at less than 110 percent of SAFMR in ZCTAs where the SAFMR is more than 110 percent of the Metropolitan Area FMR. The applicant PHAs must submit the calculation as well as the full listing of ZCTAs that represent their service areas.

Category B (Consortia With High-Performing FSS Program)

PHAs are eligible to participate under Category B as a (i) consortium, (ii) planned consortium, (iii) planned single HCV funding contract consortium, or (iv) planned partial consortium of PHAs, so long as the consortium includes at least one agency with a high-performing FSS program.

PHAs must specify the type of consortium they are in or intend to form if selected for the demonstration under Category B. PHAs applying as a consortium or planned consortium must submit the current or planned consortium agreement.

PHAs applying as a proposed single HCV funding contract consortium or partial consortium must submit a narrative description of their proposal, including the combined jurisdiction of the PHAs participating in the consortium. PHAs must identify any regulatory waivers or alternative requirements necessary to implement a planned single HCV funding contract consortium or partial consortium under this category.

Under a single HCV funding contract consortium or partial consortium, PHAs will execute an agreement among participating PHAs which governs the formation and operation of the consortium. Only PHAs selected for the demonstration will be allowed to enter into the single HCV funding contract consortium or partial consortium agreement and shall submit an unexecuted agreement as part of their application. In addition to any requirements under PIH Notice 2018–12 and 24 CFR part 943, the agreement must specify the following:

- The names of the participating PHAs;
- A description of whether the consortium is forming using a transfer or a consolidation;
- The period of existence of the consortium and the terms under which a PHA may join or withdraw from the consortium before the end of that period;
- A statement acknowledging that if the PHAs decide to dissolve the consortium and reverse the transfer or consolidation of funding and units, PHAs will inform HUD on how funds and units are distributed to participating PHAs;
- The name of the lead agency;
- The functions to be performed by the lead agency and the other participating PHAs; and
- If selected, the proposed agreement must be signed by an authorized representative of each participating PHA.

In addition to documentation related to the consortium, PHAs applying under Category B must identify the PHA(s) that operates an FSS program. HUD will consider any agency that has an FSS program to have a high-performing FSS program.[34]

Category C (Consortia With Small PHA)

PHAs are eligible to participate under Category C as either (i) consortium, (ii) planned consortium, (iii) planned single HCV funding contract consortium, or (iv) planned partial consortium of PHAs so long as they serve jurisdictions within a single region, include one or more small agencies, and consolidate mobility-focused operations.

PHAs must specify the type of consortium they are in or intend to form if selected for the demonstration under Category B. PHAs applying as a consortium or planned consortium must submit the current or planned consortium agreement.

PHAs applying as a proposed single HCV funding contract consortium or partial consortium must submit a narrative description of their proposal, including the combined jurisdiction of the PHAs participating in the consortium. PHAs must identify any regulatory waivers or alternative requirements necessary to implement a planned single HCV funding contract consortium or partial consortium under this category.

Under a single HCV funding contract consortium or planned partial consortium, PHAs will execute an agreement among participating PHAs which governs the formation and operation of the consortium. Only PHAs selected for the demonstration will be allowed to enter into the single HCV funding contract consortium or partial consortium agreement and shall submit an unexecuted agreement as part of their application. In addition to any requirements under PIH Notice 2018–12 and 24 CFR part 943, the agreement must specify the following:

- The names of the participating PHAs;
- A description of whether the consortium is forming using a transfer or a consolidation;
- The period of existence of the consortium and the terms under which a PHA may join or withdraw from the consortium before the end of that period;
- A statement acknowledging that if the PHAs decide to dissolve the consortium and reverse the transfer or consolidation of funding and units, PHAs will inform HUD on how funds and units are distributed to participating PHAs;
- The name of the lead agency;
- The functions to be performed by the lead agency and the other participating PHAs; and
- The proposed agreement must be signed by an authorized representative of each participating PHA.

In addition to documentation related to the consortium, PHAs applying under Category C must identify the small PHA(s) and the number of ACC units administered by the small PHA(s). For the purposes of the demonstration, a small PHA is defined as an agency for which the sum of the number of public housing dwelling units administered by the agency and the number of vouchers under Section 8(o) of the 1937 Act is 550 or fewer (from paragraph (a)(2)(A) of 42 U.S.C. 1437z–10).

[33] Only PHAs with 100 or more voucher families with children are included on the ranking list.

[34] The 2020 Appropriations Act limits HUD's ability to make awards based on an FSS performance measurement system.

PHAs must identify how they will consolidate mobility-focused operations. PHAs must identify the region in which the demonstration will be implemented. The region is generally defined as the metropolitan statistical area. However, there may be exceptional circumstances for PHAs to designate an alternative geography as their region. For example, an applicant might designate a state as the region when the consortium includes an agency with statewide voucher administration authority. It might also be the case that an application proposes to use a county or group of counties as the proposed region, depending on PHA service areas and market conditions. HUD will consider such proposals as alternatives to the use of MSAs. HUD also recognizes that PHAs are still subject to their own state and local requirements for authority to operate and administer HCVs.

Category D (Single Agency)

Paragraph (b)(1)(D) of Section 235 of Title II of the 2019 Appropriations Act authorizes HUD to establish other categories of PHAs that are eligible to participate in the demonstration. Under this authority, HUD has established that any single agency that otherwise meets the requirements under Category A is eligible to participate in the demonstration. To document eligibility, the agency must define where the demonstration will be implemented. An example of this is if the applicant is a statewide agency, identify the metropolitan area(s) of focus. Another example is if the applicant is a large, regional agency, identify the neighborhoods of focus. The single agency must otherwise follow the documentation requirements described in Category A.

Part L Program Specific Certifications

Each participating PHA, as part of a joint PHA application or a single agency application, must submit the following certifications as part of their individual Funding Application Form HUD–52515. This part has no page limit. Each PHA must certify that:

1. The PHA will adopt the required waiting list preference and will update its PHA Plan and Administrative Plan to incorporate the preference.

2. The PHA will update its PHA Plan and Administrative Plan, as applicable, to implement policies adopted as part of the demonstration.

3. The PHA will work together with HUD to finalize mobility-related services, opportunity areas, and other components of the demonstration.

4. The PHA will offer the agreed upon CMRS and SMRS, even if that may differ from their submitted proposal.

5. The PHA will adopt adequate payment standards in opportunity areas. Payment standards will be finalized with HUD after selection, and the same payment standard will be offered to families in the treatment and control groups.

6. The PHA will offer mobility-related services until such time as an adequate sample size has been attained, or service funding has been expended, whichever comes first.

7. The PHA will sign a memorandum of understanding and a performance standards agreement with HUD to indicate agreement with the finalized program design, services, opportunity areas, and other components of the demonstration OR sign a declaration of withdrawal from the demonstration if the PHA does not agree to the finalized services, opportunity areas, and other components of the demonstration. Should the PHA decide it no longer wants to participate in the demonstration, the PHA must inform HUD prior to implementation. PHAs will not be allowed to withdraw from the demonstration without HUD approval after the implementation date.

8. The PHA will adhere to the program performance standards agreement between HUD and the PHA, executed after selection, that describes terms and conditions of participation, including, but not limited to: Utilization requirements, recapture and reallocation terms, and a payment schedule for mobility-related services.

9. The PHA certifies that the information provided on HUD Form-2880 and HUD Form-52515 and in any accompanying documentation is true and accurate. The PHA acknowledges that making, presenting, or submitting a false, fictious, or fraudulent statement, representation, or certification may result in criminal, civil, and/or administrative sanctions, including fines, penalties, and imprisonment.

Application for Federal Assistance Form SF–424

Standard Form 424 (SF–424) is the Family of government-wide forms required to apply for Federal Assistance Programs, which provide discretionary Federal grants and other forms of financial assistance. Applicants for this Federal assistance program must sign and submit all required forms in the SF–424 Family of forms, including SF–424B.

For joint PHA applicants, each participating PHA that requests MDVs must complete the Application for Federal Assistance Form SF–424, including SF–424B. The request for mobility-related service funding should be included as part of the lead PHA's Form SF–424. Each single agency applicant also must complete these forms.

For the questions in SF–424 identified in table 7 below, HUD recommends the following answers:

TABLE 7: RECOMMENDED ANSWERS TO QUESTIONS IN SF–424

Question 2	Check ''New.''
Question 5a	The Federal Identifier requested in 5a is the PHA code of each applicant PHA (*e.g.*, MD035 or AK002).
Question 5b	Leave blank.
Question 15	You may choose the title. However, we suggest using the name (or abbreviation) of your PHA plus HCV Mobility Demonstration.
Question 16	If the location of your office and the location of the program/project is within the same Congressional District, you should indicate the same answer for both parts.
Question 17	Most applicants should indicate Month, Date, Year—Month, Date Year. However, this is an estimate and the actual dates will be determined at grant agreement.
Question 18	Will be the funding amount requested from HUD in this HCV mobility demonstration Notice. Each PHA, whether part of a joint or single PHA application, requesting MDVs must estimate their funding needs. PHAs should do this by determining the HAP amount (based on the Voucher Management System or VMS) needed to fund a 3-bedroom unit for 12 months. Then the PHA should multiply this number by the number of vouchers they would like to be awarded. Enter this number in 18a. Do not include administrative fees in this amount. Administrative fees will be paid based on vouchers leased, however, they are not factored into the award amount.

TABLE 7: RECOMMENDED ANSWERS TO QUESTIONS IN SF–424—Continued

	For joint applicant PHAs, the lead PHA must also include the total requested amount of mobility-related service dollars. Enter this in 18e. Single agency applicants must also include the total requested amount of mobility-related service dollars. Enter this number in 18e.
Question 19	Answer c. Program is not covered by Executive Order 12372.

Intergovernmental Review

This program is not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

Other Submission Requirements

Application Certifications and Assurances

By signing the forms in the SF–424 the applicant and the signing authorized representative affirm that they have reviewed the certifications and assurances associated with the Application for Federal Assistance. Additionally the authorized representative (1) are aware that the submission of the SF–424 is an assertion that the relevant certifications and assurances are established, and (2) acknowledge that the truthfulness of the certifications and assurances are material representations upon which HUD will rely when making an award to the applicant. If it is later determined that the signing authorized representative made a false certification or assurance, caused the submission of a false certification or assurance, or did not have the authority to make a legally binding commitment for the applicant, the applicant and the authorized representative may be subject to administrative, civil, or criminal action. Additionally, HUD may terminate the award to the applicant organization or pursue other available remedies. Each applicant is responsible for including the correct certifications and assurances with its application submission, including those applicable to all applicants, those applicable only to Federally recognized Indian tribes, and those applicable to applicants other than Federally-recognized Indian tribes.

Lead Based Paint Requirements

When providing education or counseling on buying or renting housing that may include pre-1978 housing, and when required by regulation or policy, applicants must inform clients of their rights under the Lead Disclosure Rule (24 CFR part 35, subpart A), and, if the focus of the education or counseling is on rental or purchase of HUD-assisted pre-1978 housing, the Lead Safe Housing Rule (subparts B, R, and, as applicable, F–M).

VIII. Rating Factors

PHAs must meet all eligibility criteria described in *Section VII Application Format.* PHAs must also submit an application in the format required by *Section VII Application Format.* PHAs can receive up to 100 points for their application, in accordance with the rating factors specified in this section. The rating factor scores that PHAs receive will be used to help rank PHAs for funding. HUD may rely on performance monitoring and audit reports, financial status information, and other information available to HUD to make selection and funding determinations. For Rating Factors 1 and 2 below, the joint or single agency applicants must submit documentation, described *in Section VII Application Format,* to earn points. For Rating Factor 3, HUD completed a regional need analysis and will assign points based on that analysis, as well as the PHA service area, which is described *in Section VII Application Format.* Applicants do not need to submit any additional information in their application for Rating Factor 3.

Rating Factor 1: Approach To Implementing the Demonstration (40 Points)

As required by the Appropriations Acts, PHAs are required to submit a Regional Housing Mobility Plan (RHMP). In the Approach to Implementing the Demonstration Rating Factor, HUD will be evaluating the PHA's RHMP and overall approach to implementing the demonstration, with the understanding that the final set of services will be decided collaboratively after selection. No PHA will receive more than 40 points for this factor. The following will be evaluated:

1. Approach to implementing the Regional Housing Mobility Plan (6 points);

2. Approach to implementing the evaluation and enrollment plan (5 points);

3. Available applicants and program participants to meet requirements of research evaluation design (10 points);

4. Jurisdictional and regional reach of mobility program (5 points);

5. Approach to implementing mobility-related services (10 points);

6. Proposed administrative policies (2 points); and

7. Proposed opportunity areas and payment standards (2 points).

Rating Factor 2: Prior Experience (30 Points)

Implementation of the demonstration will be a complex and collaborative effort between HUD and the selected PHAs. In this rating factor, HUD will evaluate a PHA's prior experiences to gauge the PHA's capacity to implement the demonstration. No PHA will receive more than 30 points for this factor. The following elements of prior experience will be evaluated:

1. Prior experience implementing policies and/or programs that promote housing choices for families with children, particularly policies and/or programs that promote expanded choices in opportunity areas. Experience implementing a housing mobility program or other mobility related services will be considered under this subfactor (10 points);

2. Prior experience implementing and administering federal, state, local or non-profit grants, programs or activities that demonstrate PHA capacity, which may include, but are not limited to: Special purpose vouchers (*e.g.* HUD–VASH, Family Unification, Mainstream vouchers, etc.), the Rental Assistance Demonstration, LIHTC, CDBG, HOPE VI or Choice Neighborhoods grants (5 points);

3. Prior experience working together with other PHAs on a regional basis, such as engaging in regional efforts around portability or other collaborations (5 points);

4. Prior experience of applicant PHAs in participating in randomized controlled trial, research, evaluations, or demonstrations, such as quantitative or qualitative research, or other experiences with data analysis and/or mapping (5 points); and

5. Prior experience managing HCV waiting lists, utilization, and success rate effectively (5 points).

Rating Factor 3: Regional Need and Available Rental Units (30 Points)

For the demonstration to be successful, PHAs must have adequate number of voucher holders with children living in neighborhoods with

high concentrations of poverty. HUD ranked all PHAs that serve over 100 families with children in two separate voucher holder concentration categories. The categories are: (1) Number of voucher holders with children in the PHA's jurisdiction living in Census tracts that have greater than 25 percent poverty or are qualified Census tracts (QCTs) as defined under the LIHTC program, and (2) percentage of voucher holders with children living in Census tracts that have greater than 25 percent poverty or are qualified Census tracts (QCT) in the PHA's jurisdiction, as defined under the LIHTC program.[35]

Within these two categories, HUD then ranked PHAs from one to five based on the degree of concentration with five being the highest concentration. This categorical ranking information based on concentration is provided at *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/mobilitydemo.*

HUD will use the highest ranking earned by the PHA in either category.

For single agency applicants (Category D) a rank of five earns 30 points; a rank of four earns 20 points; and a rank of three earns 10 points. All others get zero points.

For joint PHA applicants, if one or more PHA has a rank of five, the application gets 30 points. If no PHA has a rank of five, but one or more has a rank of four, the application gets 20 points. If no PHA has a rank of four or five, but one or more PHA has a rank of three, the application gets 10 points. All others get zero points.

IX. Application Deadlines

Contact Information and Due Dates

Each application must be submitted electronically as a PDF or Microsoft Word document (1997 version or higher) to *HCVmobilitydemonstration@hud.gov.* The subject line of the submittal email must read ''[Insert PHA Code]: Housing Choice Voucher Mobility Demonstration Program.'' The body of the email must include the name of the person submitting the application. The lead agency shall be responsible for submitting the application to HUD, no later than October 13, 2020. Applications that are submitted after midnight on October 13, 2020, or fail to include the required elements, will be ineligible for consideration by HUD.

[35] The data sources for these requirements are described in the tools and spreadsheets available at *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/mobilitydemo.*

Extensions

HUD may extend the application deadline for any program if *HUD.gov* systems are offline or not available to applicants for at least 24 hours immediately prior to the deadline date, or if the system is down for 24 hours or longer and that impacts the ability of applicants to cure a submission deficiency within the grace period.

HUD may also extend the application deadline upon request if there is a presidentially-declared disaster in the applicant's area. If these events occur, HUD will post a notice on its website establishing the new, extended deadline for the affected applicants.

Amending or Resubmitting an Application

Before the submission deadline, PHAs may resubmit a revised application containing new or changed material. The resubmitted application must be received by the applicable deadline. If HUD receives an original and a revised application for a single proposal, HUD will only evaluate the last submission received before the deadline.

Late Applications

An application received after the deadline date will be marked late and will not be reviewed by HUD for funding consideration.

Corrections to Deficient Applications

HUD will not consider information from applicants after the application deadline. HUD may contact the applicant to clarify information submitted prior to the deadline. Deficiencies typically involve missing documents, information on a form, or some other type of unsatisfied information request (*e.g.,* an unsigned form, unchecked box). Depending on specific criteria, deficiencies may either be curable or non-curable.

A curable deficiency is an error or oversight that, if corrected, would not alter, in a positive or negative fashion, the rating of the application. To be a curable deficiency, it must not be an eligibility criterion, with the following exceptions: (1) Documentation of applicant eligibility, and (2) miscategorized applicant eligibility (Category A, B, C or D). Since these exceptions will not influence how an applicant is ranked or scored against other applicants, it can be remedied within the time frame specified in the notice of deficiency. HUD will uniformly notify applicants of each curable deficiency. A non-curable deficiency is one that, if corrected, would change an applicant's score or rank. Non-curable deficiencies may result in an application being marked ineligible, or otherwise adversely affect an applications' score and final determination.

Applicants must email corrections of curable deficiencies to *HCVmobilitydemonstration@hud.gov* within the time limits specified in the notification. The time allowed to correct deficiencies will be no less than 48 hours and no more than 14 calendar days from the date of the notification.

X. Application Review Process

After the application deadline, HUD will review all applications that meet the eligibility criteria. Following the evaluation process, HUD will notify successful applicants of their selection for funding. HUD will also notify other applicants, whose applications were received by the deadline, but have not been selected for the demonstration.

Past Performance

When evaluating applications for funding, HUD will, whenever possible, obtain past performance information to confirm certifications claimed by the PHA.

HUD will also consider an applicant's past performance in managing funds. Items HUD may consider include, but are not limited to:

- The ability to account for funds appropriately;
- Timely use of funds received from HUD;
- Timely submission and quality of reports submitted to HUD;
- Meeting program requirements;
- Meeting performance targets as established in the grant agreement;
- The applicant's organizational capacity, including staffing structures and capabilities;
- Timelines for completion of activities and receipt of promised matching or leveraged funds; and
- The number of persons to be served or targeted for assistance.

Negotiation

After HUD has made selections, HUD may negotiate specific terms of the funding agreement and budget with selected applicants. If HUD and a selected applicant do not successfully conclude negotiations in a timely manner, or a selected applicant fails to provide requested information, an award will not be made to that applicant. In this case, HUD may select another eligible applicant.

Special Conditions

HUD may impose special conditions on an award as provided under 2 CFR 200.207:

• Based on HUD's review of the applicant's risk under 2 CFR 200.205;

• When the applicant or recipient has a history of failure to comply with the general or specific terms and conditions of a Federal award;

• When the applicant or recipient fails to meet expected performance goals; or

• When the applicant or recipient is not otherwise responsible.

Adjustments to Funding

To ensure the fair distribution of funds and enable the purposes or requirements of a specific program to be met, HUD reserves the right to fund less than the amount requested in an application.

If funds are available after funding the highest-ranking application, HUD may fund all or part of another eligible fundable application. If an applicant turns down an award offer, or if HUD and an applicant do not successfully complete grant negotiations, HUD may make an offer of funding to another eligible application.

If funds remain after all selections have been made, remaining funds may be made available within the current fiscal year for initial awardees in shortages, where the initial per unit cost (PUC) considered for the vouchers was insufficient to fully lease up the voucher awarded, due to market conditions or other justifiable causes. HUD is limited to up to $10 million total for HAP funds whether or not that is sufficient to fully lease up authorized MDVs awarded to PHAs. The remainder of the total funding made available under this notice is for mobility-related services and HUD is limited by that amount.

If, after announcement of awards made under the current notice, additional funds become available either through the current appropriations, a supplemental appropriation, other appropriations or recapture of funds, HUD may use the additional funds to provide additional funding to an applicant awarded less than the requested amount of funds to make the full award, and/or to fund additional applicants that were eligible to receive an award but for which there were no funds available.

Funding Errors

If HUD makes an error that when corrected would cause selection of an applicant during the funding round of this notice, HUD may select that applicant for funding, subject to the availability of funds.

XI. Administrative, National, and Department Policy Requirements for HUD Recipients

For this notice, the following administrative, national and department policy requirements and terms for HUD financial assistance awards apply.

These non-discrimination and equal opportunity authorities and other requirements apply to all competitive awards.

• Compliance with fair housing and civil rights laws, which encompass the Fair Housing Act and related authorities (24 CFR 5.105(a)).

• Affirmatively furthering fair housing.

• Improving access to services for persons with limited English proficiency (LEP).

• Accessible technology.

• Equal access to housing regardless of sexual orientation or gender identity.

• Equal participation of Faith-Based organizations in HUD programs and activities.

• Participation in HUD-sponsored program evaluation.

• Accessibility for persons with disabilities.

• Violence Against Women Act.

• Environmental Requirements: In accordance with 24 CFR 50.19(b)(1), (3), (11) and (12); and 24 CFR 58.34(a)(1) and (3); and 24 CFR 58.35(b)(1) and (2); activities funded under this notice are exempt or categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321, *et seq.*) and not subject to environmental review under related laws and authorities.

Further information on each applicable criteria can be found here: General Administration Requirements and Terms for HUD Assistance Awards (*https://www.hud.gov/sites/dfiles/SPM/documents/Gen_Admin_Req_Terms-FY19-HUD.Assistance.Awards.docx?web=1*).

XII. Reporting and Recordkeeping Requirements

Federal Audit Reporting

HUD requires recipients to submit performance and financial reports under Office of Management and Budget (OMB) guidance and program instructions.

Applicants should note that if the total Federal share of an applicant's Federal award includes more than $500,000 over the period of performance, the applicant may be subject to post award reporting requirements reflected in 2 CFR part 200, appendix XII-Award Term and Condition for Recipient Integrity and Performance Matters.

Public and Indian Housing Information Center (PIC) Reporting

Under the demonstration program, PHAs will be required to follow HUD requirements for PIC reporting. This may include using new program codes on line 2n of Form HUD–50058 (*e.g.,* MDV). PHAs must agree to 100 percent PIC reporting for the MDVs, including submission of voucher issuance date and voucher expiration date.

Voucher Management System Reporting

PHAs will be required to follow HUD guidance for reporting MDV HAP and unit months leased, and mobility-related service expenditures in the Voucher Management System.

Reporting on non-HUD Funds

PHAs will be required to follow HUD guidance on reporting related to the use of non-HUD funds contributed to the demonstration.

Performance Reporting

All HUD-funded programs, including this program, require recipients to submit, at least annually, a report documenting achievement of outcomes under the purpose of the program and the work plan in the award agreement.

Race, Ethnicity, and Other Data Reporting

HUD requires recipients that provide HUD funded program benefits to individuals or families to report data on the race, color, religion, sex, national origin, age, disability, and family characteristics of persons and households who are applicants for, participants in, or beneficiaries or potential beneficiaries of HUD programs in order to carry out the Department's responsibilities under the Fair Housing Act, Executive Order 11063, Title VI of the Civil Rights Act of 1964, and Section 562 of the Housing and Community Development Act of 1987.

Debriefing

For a period of at least 120 days, beginning 30 days after the public announcement of awards under this notice, HUD will provide a debriefing related to their application to requesting applicants. A request for debriefing must be made in writing or by email by the authorized official whose signature appears on the SF–424 or by his or her successor in office. If the request is made by email, it must be submitted to *HCVmobilitydemonstration@hud.gov.* Information provided during a debriefing may include the final score the applicant received for each rating factor, final evaluator comments for each rating factor, and the final

assessment indicating the basis upon which funding was approved or denied.

Agency Contacts

HUD staff will be available to provide clarification on the content of this notice. Questions regarding specific program requirements for this notice should be directed to *HCVmobilitydemonstration@hud.gov.* Please note that HUD staff cannot assist applicants in preparing their applications.

Other Information

National Environmental Policy Act. This Notice of Funding Availability (NOFA) provides funding under, and does not alter the environmental requirements of, 24 CFR part 982. Accordingly, under 24 CFR 50.19(c)(5), this NOFA is categorically excluded from environmental review under the National Environmental Policy Act of 1969, (42 U.S.C. 4321, *et seq.*). The environmental review provisions in 24 CFR part 982 are found at §§ 982.305(b)(3), 982.626(c), 982.628(e), 982.631(b)(3), 982.637(b). However, these environmental review provisions are not applicable to activities under this NOFA, which are exempt or categorically excluded from environmental review.

Information Collection Requirements

The information collection requirements for this demonstration have been approved by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB control number 2577–0169. In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

Dated: July 8, 2020.

R. Hunter Kurtz,

Assistant Secretary for Public and Indian Housing.

Attachment A: Mandatory SAFMR Criteria

Metropolitan FMR areas that meet the following requirements are subject to Small Area FMRs consistent with 24 CFR 888.113(c):

(i) There are at least 2,500 HCV under lease;

(ii) At least 20 percent of the standard quality rental stock, within the metropolitan FMR area is in small areas (ZIP codes) where the Small Area FMR is more than 110 percent of the metropolitan FMR;

(iii) The percentage of voucher families living in concentrated low-income areas relative to all renters within the area must be at least 25 percent;

(iv) The measure of the percentage of voucher holders living in concentrated low-income areas relative to all renters within these areas over the entire metropolitan area exceeds 155 percent (or 1.55);

(v) The vacancy rate for the metropolitan area is higher than 4 percent. The vacancy rate is calculated using data from the one-year American Community Survey (ACS) tabulations, the vacancy rate is the number of Vacant For Rent Units divided by the sum of the number of Vacant For Rent Units, the number of Renter Occupied Units, and the number of Rented, not occupied units; and

(vi) The vacancy rate will be calculated from the three most current ACS one-year datasets available and average the three values.

The metropolitan FMR Areas that meet these requirements are as follows:

Atlanta-Sandy Springs-Marietta, GA HUD Metro FMR Area
Bergen-Passaic, NJ HUD Metro FMR Area
Charlotte-Gastonia-Rock Hill, NC–SC HUD Metro FMR Area
Chicago-Joliet-Naperville, IL HUD Metro FMR Area
Colorado Springs, CO HUD Metro FMR Area
Dallas-Plano-Irving, TX Metro Division
Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Metro Division
Fort Worth-Arlington, TX HUD Metro FMR Area
Gary, IN HUD Metro FMR Area
Hartford-West Hartford-East Hartford, CT HUD Metro FMR Area
Jackson, MS HUD Metro FMR Area
Jacksonville, FL HUD Metro FMR Area
North Port-Bradenton-Sarasota, FL MSA
Monmouth-Ocean, NJ HUD Metro FMR Area
Palm Bay-Melbourne-Titusville, FL MSA
Philadelphia-Camden-Wilmington, PA–NJ–DE–MD MSA
Pittsburgh, PA HUD Metro FMR Area
Sacramento-Arden-Arcade-Roseville, CA HUD Metro FMR Area
San Antonio-New Braunfels, TX HUD Metro FMR Area
San Diego-Carlsbad-San Marcos, CA MSA
Tampa-St. Petersburg-Clearwater, FL MSA
Urban Honolulu, HI MSA
Washington-Arlington-Alexandria, DC–VA–MD HUD Metro FMR Area
West Palm Beach-Boca Raton-Delray Beach, FL Metro Division

Attachment B: Alternative Requirements for Single HCV Funding Contract Consortia

PHAs submitting an application for the demonstration under Category B, Consortia with High-Performing FSS Program or Category C, Consortia with Small PHA may use these alternative requirements in place of 24 CFR part 943, subpart B, for Single HCV Funding Contract Consortia if selected. Please see *Section VI Waivers and Alternative Requirements for the Demonstration* for further information on alternative requirements and *Section VII Application Format* on applying for the demonstration.

1. Purpose of these alternative requirements.

These alternative requirements authorize public housing agencies (PHAs), consistent with State and local law, to form consortia under Section 13 of the United States Housing Act of 1937 (42 U.S.C. 1437k) (1937 Act) for the purpose of the HCV mobility demonstration.

2. Single-HCV Consortium.

A single HCV funding contract consortium consists of two or more PHAs that join together to perform planning, reporting, and other administrative and management functions of the Section 8 Housing Choice Voucher (HCV) program, as specified in a consortium agreement. Under a single HCV funding contract consortium, the consortium becomes a separate legal entity and is considered a single PHA for purposes of the Section 8 HCV program. A single HCV funding contract consortium must operate the Section 8 HCV program in accordance with all applicable program regulations. HUD funds the consortium as one PHA and applies all reporting and audit requirements accordingly.

3. Programs covered under these requirements.

(a) A PHA may enter a single HCV funding contract consortium under these requirements solely for the implementation of the demonstration under the Section 8 HCV program (including project-based vouchers; project-based certificates; and special voucher housing types, including the HCV Homeownership Option).

(b) Moving-To-Work (MTW) PHAs may not form or join a single HCV funding contract consortium.

4. Organization of a single HCV funding consortium.

(a) A PHA that elects to form a single HCV funding contract consortium may do so upon HUD approval after selection for the demonstration, and in accordance with HUD-established

guidelines and instructions. HUD approval after selection for the demonstration of a single HCV funding contract consortium will be based on the following:

(1) That all required documentation has been submitted including:

(i) The Consortium Agreement;

(ii) The 5-Year Plan and the Annual Plan, as applicable, in accordance with 24 CFR part 903 and any other statutory or HUD requirements (See section 12 of these requirements, Planning, reporting, and financial accountability);

(iii) A letter of intent signed by the executive director of every PHA wishing to join the single HCV funding contract consortium, with an accompanying board resolution of each PHA;

(iv) Supporting legal opinions satisfactory to HUD that the single HCV funding contract consortium's jurisdiction is consistent with the state and local laws of each consortium member;

(v) Financial documentation for each PHA wishing to join the single HCV funding contract consortium, including a final close-out audit for every PHA joining the single HCV funding contract consortium, up to the effective date of the consortium;

(vi) Certification that each PHA in the consortium has resolved all outstanding civil rights matters to HUD's satisfaction; and

(A) The PHA wishing to join takes corrective action to the satisfaction of HUD or another entity with authority to enforce a corrective action agreement or order; or

(B) The single HCV funding contract consortium demonstrates to HUD's satisfaction that it has assumed liability for taking the corrective action; and

(vii) Any other form of documentation that HUD deems necessary and appropriate for approval of the single HCV funding contract consortium;

(3) The PHA's performance rating under the Section 8 Management and Assessment Program (SEMAP), and whether there are any open findings from an Office of Inspector General (OIG) audit, HUD Field Office (FO) monitoring review, financial audit, and/or any other HUD or HUD-required review;

(4) That the financial documentation submitted by each PHA in support of single HCV funding contract consortium formation demonstrates that the single HCV funding contract consortium will have the financial capability, as determined by HUD, to administer the programs and activities of the single HCV funding contract consortium, including the demonstration;

(5) Any other factors that may indicate appropriateness of single HCV funding contract consortium formation, such as the PHA's capacity to administer its Section 8 HCV program, and the existing market conditions in the jurisdiction of each PHA joining the single HCV funding contract consortium; and

(6) That all other consortium requirements are met.

(b) A PHA that elects to form a single HCV funding contract consortium must enter into a consortium agreement, which shall meet the minimum requirements established in section 6 of these requirements (Elements of a single HCV funding contract consortium agreement) of these requirements. The executed consortium agreement must be submitted to HUD, and HUD may require modification to the consortium agreement before approving the formation of the single HCV funding contract consortium.

(c) PHAs joining a single HCV funding contract consortium must adopt a new fiscal year end for the consortium.

(d) The single HCV funding contract consortium must be administered in accordance with the applicable provisions of these requirements; the consortium agreement; the PHA Plan, as applicable; other applicable HUD regulations and requirements; and State and local law.

5. Jurisdiction of a single HCV funding contract consortium.

(a) A single HCV funding contract consortium shall operate in a single consortium-wide jurisdiction composed of the combined jurisdictions of all consortium members. Jurisdictional boundaries between individual consortium members will cease to exist for purposes of HCV program administration during the term of the consortium.

(b) The single HCV funding contract consortium jurisdiction must be consistent with the State and local law of each consortium member.

6. Elements of a single HCV funding consortium agreement.

(a) The single HCV funding contract consortium agreement governs the formation and operation of the consortium and must specify the following:

(1) The name of each consortium member under the consortium agreement;

(2) The functions to be performed by each consortium member during the term of the consortium, including for the demonstration;

(3) The structure of the single HCV funding contract consortium, which shall address, at a minimum, the establishment of a board of directors or similar governing body and designated officials;

(4) The process for merging the consortium members' waiting lists upon formation of the single HCV funding contract consortium, including the adoption of waiting list preferences (*e.g.,* homeless) by the single HCV funding contract consortium. This process must not have the purpose or effect of delaying or otherwise denying admission to the program based on race, color, national origin, sex, religion, disability, or familial status of any member of the applicant family;

(5) The terms under which a PHA may join or withdraw from the single HCV funding contract consortium. The consortium agreement shall conform to section 7 of these requirements (Withdrawals from or additions to a single HCV funding contract consortium) of these requirements;

(6) How new incremental vouchers under a special purpose voucher program will be distributed among consortium members upon dissolution or withdrawal from the consortium; and

(7) Which consortium member, upon dissolution or withdrawal, shall have jurisdiction over converted projects with overlapping jurisdictions under a multifamily housing tenant protection action.

(b) The agreement must acknowledge that all consortium members are subject to the single HCV funding contract consortiums' PHA Plan.

(c) The agreement must be signed by an authorized representative of each consortium member.

7. Withdrawals from or additions to a single HCV funding contract consortium.

(a) Withdrawal refers to one or more consortium members leaving the single HCV funding contract consortium without resulting in dissolution of the single HCV funding contract consortium.

(b) Withdrawals from a single HCV funding contract consortium may not occur until the initial consortium term has expired, which is the term of participation in the demonstration. HUD may, upon showing of good cause, allow withdrawals from a single HCV funding contract consortium before completion of the initial term.

(c) If the consortium has any outstanding civil rights matters, withdrawals from a single HCV funding contract consortium may not occur unless the withdrawal is consistent with the action(s) to resolve such matters.

(d) To provide for orderly transition, withdrawal of a PHA must take effect on the last day of the consortium's fiscal

year, and addition of a PHA must take effect on the first day of the consortium's fiscal year. The single HCV funding contract consortium must notify HUD in writing of any additions or withdrawals at least 120 days in advance. This notification must include submission of the withdrawing member's replacement 5-Year Plan and Annual Plan, as applicable, in accordance with 24 CFR part 903 and any other statutory or HUD requirements.

(e) Upon withdrawal from the single HCV funding contract consortium, the withdrawing member must offer to each applicant currently on the single HCV funding contract consortium's waiting list the opportunity to be placed on the withdrawing member's waiting list, with the date and time of their original application to the single HCV funding contract consortium's waiting list. These applicants must not be considered nonresident applicants (for the purposes of restriction of portability under § 982.353(c)) if the applicant was a resident applicant at the time of application to the single HCV funding contract consortium's waiting list.

(f) Upon a member's withdrawal from the single HCV funding contract consortium, vouchers and funding, including net restricted assets and unrestricted net assets, will be distributed to the withdrawing member as specified in section 9 of these requirements (voucher and funding distribution upon dissolution or withdrawal) of these requirements.

8. Dissolution of a single HCV funding contract consortium.

(a) A single HCV funding contract consortium may not be dissolved during the demonstration. HUD may, upon showing of good cause, allow dissolution of a consortium prior to completion of the demonstration. A single HCV funding contract consortium will continue to exist beyond the demonstration, unless dissolved.

(b) If the consortium has any outstanding civil rights matters, dissolution of a single HCV funding contract consortium may not occur unless the dissolution is consistent with the action(s) to resolve such matters.

(c) To provide for orderly transition, dissolution of the single HCV funding contract consortium must take effect on the last day of the consortium's fiscal year. The single HCV funding contract consortium must notify HUD in writing of dissolution at least 120 days in advance of the dissolution effective date. This notification must include submission of all members' replacement 5-Year Plans and Annual Plans, as applicable, in accordance with 24 CFR part 903 and any other statutory or HUD requirements.

(d) Upon dissolution, all withdrawing members must offer to each applicant currently on the single HCV funding contract consortium's waiting list the opportunity to be placed on all of the withdrawing members' waiting lists, with the date and time of their original application to the single HCV funding contract consortium's waiting list. These applicants must not be considered nonresident applicants (for the purposes of restriction of portability under § 982.353(c)) if the applicant was a resident applicant at the time of application to the single HCV funding contract consortium's waiting list.

(e) Upon dissolution, vouchers and funding, including net restricted assets and unrestricted net assets, will be distributed among consortium members as specified in section 9 of these requirements (voucher and funding distribution upon dissolution or withdrawal) of these requirements.

9. Voucher and funding distribution upon dissolution or withdrawal.

(a) Vouchers will be distributed in the following manner upon dissolution or withdrawal:

(1) Each consortium member will leave the consortium upon dissolution or withdrawal with at least the same number of authorized baseline units that the consortium member brought into the consortium at the time of its formation. HUD may, for good cause, allow for an alternative distribution of baseline units.

(2) Each consortium member shall receive contract renewal funding allocations based on the number of leased vouchers located within their original jurisdiction at the time of withdrawal or dissolution, up to their original baseline number. HUD may, for good cause, allow for an alternative distribution of leased vouchers.

(3) Tenant protection vouchers allocated to cover a public housing demolition, disposition, or conversion action will remain with the PHA that has ownership over the property. Tenant protection vouchers allocated to cover a multifamily housing conversion action shall remain with the PHA that has jurisdiction over the converted project. Administration of tenant protection vouchers under converted projects with overlapping jurisdictions shall remain with the PHA that has jurisdiction over the converted project as specified in the consortium agreement.

(4) New incremental vouchers under a special purpose voucher program will be distributed as specified in the consortium agreement, provided that such voucher distribution is made in accordance with program requirements under each respective special purpose voucher program.

(b) Funding will be distributed in the following manner upon dissolution or withdrawal:

(1) Budget authority will be divided proportionately, based on the percentage of all leased units in the consortium that each consortium member will receive.

(2) Administrative fees will be paid to the withdrawing PHA and the remaining consortium per the current appropriations requirements.

(3) Net Restricted Assets and Unrestricted Net Assets will be distributed based upon the percentage of the initial balance that was contributed by each consortium member.

10. The relationship between HUD and a single HCV funding contract consortium.

(a) HUD has a direct relationship with the single HCV funding contract consortium, the same as it would have with any other PHA. Program funds will be disbursed to the single HCV funding contract consortium in accordance with the consortium's ACC. Funding must be used in accordance with the consortium agreement, the PHA Plan, the demonstration, and HUD regulations and requirements.

(b) HUD may take any of the remedies described in the ACC against an individual member in a single HCV funding contract consortium, or against the single HCV funding contract consortium as a whole, if it determines that either has substantially violated—or is improperly administering—the requirements of the HCV program or the demonstration.

11. Organizational costs and administrative fees.

(a) The administrative fee for a single HCV funding contract consortium will be determined based on the published administrative fee rates for the area in which the single HCV funding contract consortium has the greatest proportion of its participants on a date in time and the total number of vouchers under lease for the single HCV funding contract consortium as of the first of the month, up to the baseline number of vouchers under the single HCV funding contract consortium's ACC.

(b) A single HCV funding contract consortium may apply to HUD for blended rates, which are determined based on a weighted average of the published administrative fee rates for all areas in which program participants are located within the single HCV funding contract consortium and all participants

under lease in each of the areas on a date in time. The blended rates will be based on the published administrative fee rate for each consortium member, effective for the year for which the blended rate is requested. Blended rates will only be applied if they result in a higher administrative fee rate for the single HCV funding contract consortium. Blended rates apply only to the year for which requested.

(c) If appropriations are available, a single HCV funding contract consortium may be eligible for a higher administrative fee in accordance with 24 CFR 982.152(b)(2) if it operates over a large geographic area.

(d) If appropriations are available, a single HCV funding contract consortium may be eligible for administrative fees to cover extraordinary costs determined necessary by HUD, in accordance with 24 CFR 982.152(a)(1)(iii)(C), during the initial year of operation of the consortium to provide for the organization and implementation of the single HCV funding contract consortium.

12. Planning, reporting, and financial accountability.

(a) A single HCV funding contract consortium is considered one PHA for purposes of Section 8 HCV program administration, including but not limited to, program accounts and records, audit requirements, and all PHA responsibilities under the ACC, the PHA administrative plan, and HUD regulations and other requirements, including the demonstration.

(b) Planning, reporting, and financial accountability apply to a single HCV funding contract consortium as follows:

(1) Upon creation of the single HCV funding contract consortium, each member's assets, liabilities, and equity accounts, as related to the HCV program, are consolidated and reported on a consolidated balance sheet for purposes of single reporting in the Financial Assessment Subsystem for Public Housing Agencies (FASS–PH) and the Voucher Management System (VMS).

(2) Prior to entering a single HCV funding contract consortium, each PHA must agree to the completion of a final audit to close-out program accounts for all HCV programs, up to the effective date of the consortium. The final audit must be completed in accordance with 24 CFR 982.159. Once the audit is completed, remaining funds from all the PHAs' accounts must be transferred to the consortium.

(3) During the term of the consortium agreement, the single HCV funding contract consortium must submit a 5-Year Plan and Annual Plan, as applicable, for the consortium, in accordance with 24 CFR part 903 and any other statutory or HUD requirements. For any programs not covered by the single HCV funding contract consortium (*e.g.,* a consortium member administers a public housing program separately from the single HCV funding contract consortium), consortium members must submit a separate 5-Year Plan and Annual Plan to HUD for those programs, as applicable, in accordance with 24 CFR part 903 and any other statutory or HUD requirements.

(4) During the term of the consortium agreement, the single HCV funding contract consortium must have a single Section 8 HCV administrative plan for the consortium, in accordance with 24 CFR 982.54 (Administrative plan).

(5) The single HCV funding contract consortium must maintain records and submit reports to HUD as a single PHA for purposes of Section 8 HCV program administration and the demonstration, in accordance with HUD regulations and requirements that account for all activities of the consortium. All consortium members will be bound by the 5-Year and Annual Plans and reports submitted to HUD by the single HCV funding contract consortium for programs covered by the consortium.

(6) Financial accountability rests with the single HCV funding contract consortium and, thus, HUD will apply independent audit and performance assessment requirements on a consortium-wide basis.

(7) A single HCV funding contract consortium must keep a copy of the consortium agreement on file for inspection. The consortium agreement must also be a supporting statement to the PHA plan.

13. Responsibilities of a single HCV funding contract consortium.

Each consortium member is responsible for the performance of the consortium and has an obligation to assure that all program funds are used in accordance with HUD regulations, requirements, and that the programs under the consortium are administered in accordance with HUD regulations and requirements, including the demonstration. Any breach of program requirements is a breach of the consortium ACC, so each consortium member is responsible for the performance of the consortium as a whole.

14. Responsibilities of member PHAs.

Despite participation in a consortium, each member PHA remains responsible for its own obligations under its ACC with HUD. This means that each member PHA has an obligation to assure that all program funds, including funds paid to the lead agency for administration by the consortium, are used in accordance with HUD regulations and requirements, and that the PHA's program is administered in accordance with HUD regulations and requirements, including the demonstration. Any breach of program requirements with respect to a program covered by the consortium agreement is a breach of the ACC with each of the member PHAs, so each PHA is responsible for the performance of the consortium.

[FR Doc. 2020–15037 Filed 7–14–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X LLUTC01000 L51010000 ER0000 LVRWJ18J4210; UTU–92733]

Notice of Intent To Prepare an Environmental Impact Statement and To Initiate the Public Scoping Process for the Proposed Pine Valley Water Supply Project, Beaver and Iron County, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM), intends to prepare an Environmental Impact Statement (EIS) to consider a right-of-way (ROW) application submitted by the Central Iron County Water Conservancy District (CICWCD), referred to as the Pine Valley Water Supply (PVWS) Project.

DATES: This Notice initiates the public scoping process. Scoping comments may be submitted in writing until August 14, 2020.

ADDRESSES: You may submit written comments related to the proposed actions at *https://eplanning.blm.gov/eplanning-ui/project/1503915/510,* or by email at *pvwsproject@gmail.com,* or mail at Bureau of Land Management, Attn: PVWS, 176 DL Sargent Drive, Cedar City, Utah 84721.

FOR FURTHER INFORMATION CONTACT: Michelle Campeau, Cedar City Field Office Realty Specialist, telephone (435) 865–3047; address 176 DL Sargent Dr., Cedar City, UT 84721; email *pvwsproject@gmail.com.* Persons who use a telecommunications device for the

deaf may call the Federal Relay Service (FRS) at 1–800–877–8339 to leave a message or question for the above individual. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. Replies are provided during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM will announce date(s) and location(s) of any public involvement opportunities through a news release and the BLM website at: *https://www.blm.gov/news/utah.* In order to be considered during the preparation of the Draft EIS, all comments must be received prior to the close of the 30-day scoping period or 15 days after the last public meeting, whichever is later. The BLM will provide additional opportunities for public participation upon publication of the Draft EIS.

On June 15, 2017, CICWCD applied for a ROW grant for the PVWS Project on BLM-managed public land in western Iron and Beaver counties, Utah. The proposed project would include the development of a system for the extraction and transport of water, which the CICWCD holds rights to as permitted by the Utah Division of Water Resources, from Pine Valley to Cedar Valley.

The EIS will analyze the development of 15 drilled production wells contained within above-ground well-houses, 10 of which are on BLM-managed public lands, all within the Pine Valley in Beaver County. The project also includes the development of buried feeder pipelines, access roads, above-ground power distribution lines, a solar field (on private land), large underground storage tank (on private land), and a main buried pipeline to transport water to Iron County communities. All portions of the project located on non-Federal land will be analyzed in the EIS as connected actions. The CICWCD proposed a 66.31-mile long buried water transmission pipeline, including lateral lines to connect the wells to the main line, with a total of approximately 42.61 miles of buried pipeline crossing BLM-managed public land. The CICWCD also applied for a 50-foot-wide, 30-year, 250-acre ROW, and during construction, an additional 70-foot-wide temporary ROW totaling approximately 382 acres. The CICWCD is requesting an additional width of 70 feet for temporary use along the pipeline corridor during construction. The total combined ROW width (including the ROW and the temporary ROW) during construction would be 120 feet. The BLM will prepare an EIS to consider the CICWCD application and a reasonable range of alternatives.

NEPA Process

The BLM will use an interdisciplinary approach to develop the EIS in order to consider the variety of resource issues and concerns identified during the scoping period. Potential direct, indirect, residual, and cumulative impacts from the proposed actions will be analyzed in the EIS.

The purpose of the public scoping process is to identify relevant subject areas that will influence the scope of the environmental analysis, including potential alternatives, and guide the process for developing the EIS. At present, the BLM has identified the following preliminary subject areas: Impacts to ground water, threatened and endangered species, including the federally listed Utah prairie dog, greater sage-grouse, and socioeconomic factors.

The BLM will follow the NEPA public participation requirements to satisfy the public involvement requirements under Section 106 of the National Historic Preservation Act (NHPA) (16 U.S.C. 470(f)) pursuant to 36 CFR 800.2(d)(3). Any information about historic and cultural resources within the area potentially affected by the proposed project will assist the BLM in identifying and evaluating impacts to such resources in the context of both NEPA and Section 106 of the NHPA.

The BLM will consult with Indian Tribes 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. The BLM actively coordinates with other Federal, State, and local agencies, along with Tribes and other stakeholders that may be interested in or affected by the proposed PVWS Project.

Before including your 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: 40 CFR 1502.9, 40 CFR 1506.6, 43 CFR 46.435, 43 CFR 2800.

Anita Bilbao,

Acting State Director.

[FR Doc. 2020–15300 Filed 7–14–20; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–30398; PPWOCRADP2, PCU00RP14.R50000]

National Historic Landmarks Committee of the National Park System Advisory Board; Notice of Public Meeting

AGENCY: National Park Service.

ACTION: Meeting notice.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the National Historic Landmarks Committee (Committee) of the National Park System Advisory Board (Board) will meet as indicated below.

DATES: The virtual meeting will be held on Wednesday, September 2, 2020, from 10:00 a.m. to 5:00 p.m.; and Thursday, September 3, 2020, from 10:00 a.m. to 5:00 p.m. (EDT).

ADDRESSES: The meeting will be held virtually at the date and time noted above and instructions and access information will be available online August 28, 2020 at *https://www.nps.gov/subjects/nationalhistoriclandmarks/events.htm.* Please check the program website at *https://www.nps.gov/nhl* for the most current meeting information.

FOR FURTHER INFORMATION CONTACT: Patricia Henry, Historian, National Historic Landmarks Program, National Park Service, 1849 C Street NW, Mail Stop 7228, Washington, DC 20240; telephone (202) 354–2216 or email *Patty_Henry@nps.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the meeting of the Committee is to evaluate nominations of historic properties in order to advise the Board of the qualifications of each property being proposed for National Historic Landmark designation, and to make recommendations regarding the possible designation of those properties as National Historic Landmarks to the Board at its September 16–17, 2020, meeting. The Committee also makes recommendations to the Board regarding amendments to existing designations and proposals for withdrawal of designation. The members of the Committee are:

Mr. Joseph Emert, Chair
Dr. David G. Anderson
Dr. Ethan Carr
Dr. Julio Cesar Capó
Ms. Jeanne Cyriaque
Dr. Cynthia G. Falk
Dr. Richard Longstreth
Dr. Alexandra M. Lord
Mr. John L. Nau III

Dr. Vergil E. Noble
Dr. Toni M. Prawl
Mr. Adam Smith
Mr. Boyd C. Smith
Dr. Sharita Jacobs Thompson
Dr. Carroll Van West
Dr. Richard Guy Wilson

The meeting will be open to the public. Pursuant to 36 CFR part 65, any member of the public may file, for consideration by the Committee, written comments concerning the National Historic Landmark nominations, amendments to existing designations, or proposals for withdrawal of designation.

Comments should be submitted to Sherry A. Frear, Chief, National Register of Historic Places and National Historic Landmarks Program, National Park Service, 1849 C Street NW, Mail Stop 7228, Washington, DC 20240, email *nhl_info@nps.gov* no later than September 1, 2020. All comments received will be provided to the Committee and the Board.

Purpose of the Meeting: The Board and its Committee may consider the following nominations:

Connecticut

FIRST PRESBYTERIAN CHURCH, Stamford, CT

District of Columbia

PAN AMERICAN UNION HEADQUARTERS, Washington, DC

Georgia

ANDALUSIA FARM (FLANNERY O'CONNOR HOME), Milledgeville, GA

Massachusetts

WESTERN RAILROAD STONE ARCH BRIDGES AND CHESTER FACTORY VILLAGE DEPOT, Becket, Middlefield, and Chester, MA

Michigan

MINONG COPPER MINING DISTRICT, Isle Royale National Park, Keweenaw County, MI

Nebraska

SCOUT'S REST RANCH HEADQUARTERS, North Platte, NE

New York

GRANT COTTAGE, Wilton, NY
WEST POINT FOUNDRY ARCHEOLOGIAL SITE, Cold Spring, NY

Texas

LOWER PECOS CANYONLANDS ARCHEOLOGICAL DISTRICT, Val Verde County, TX

Virginia

PATSY CLINE HOUSE, Winchester, VA
STABLER–LEADBEATER APOTHECARY SHOP, Alexandria, VA

Wisconsin

ROCK ISLAND SITE II, Rock Island State Park, Door County, WI

Proposed Amendments to Existing Designations

Connecticut

HILL–STEAD, Farmington, CT (updated documentation)

Hawaii

KALAUPAPA LEPROSY SETTLEMENT, Kalawao, HI (updated documentation)

Tennessee

HERMITAGE HOTEL, Nashville, TN (updated documentation)

Public Disclosure of Comments: 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: 36 CFR 65.5.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2020–14769 Filed 7–14–20; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1132 and 1134 (Second Review)]

Polyethylene Terephthalate Film, Sheet, and Strip From China and the United Arab Emirates; Scheduling of Expedited Five-Year Reviews.

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty orders on polyethylene terephthalate film, sheet, and strip from China and the United Arab Emirates would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: April 6, 2020.

FOR FURTHER INFORMATION CONTACT: Alejandro Orozco (202–205–3177), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On April 6, 2020, the Commission determined that the domestic interested party group response to its notice of institution (85 FR 114, January 2, 2020) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of these reviews will be placed in the nonpublic record on July 20, 2020, and made available to persons on the Administrative Protective Order service list for these reviews. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the joint response to its notice of institution filed on behalf of four domestic producers (DuPont Teijin Films,

other than an interested party to the reviews may file written comments with the Secretary on what determinations the Commission should reach in the reviews. Comments are due on or before July 27, 2020 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by July 27, 2020. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules with respect to filing were revised effective July 25, 2014. *See* 79 FR 35920 (June 25, 2014). The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determinations.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: July 9, 2020.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2020–15197 Filed 7–14–20; 8:45 am]

BILLING CODE 7020–02–P

Mitsubishi Polyester Film, Inc., SKC, Inc., and Toray Plastics (America), Inc., and a second response filed individually by another domestic producer (Terphane LLC) to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–656 and 731–TA–1533 (Preliminary)]

Metal Lockers From China; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–656 and 731–TA–1533 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of metal lockers from China, provided for in subheadings 9403.20.00 (9403.20.0078) and 9403.90.80 (9403.90.8041) of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by August 24, 2020. The Commission's views must be transmitted to Commerce within five business days thereafter, or by August 31, 2020.

DATES: July 9, 2020.

FOR FURTHER INFORMATION CONTACT: Celia Feldpausch (202) 205–2387), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to petitions filed on July 9, 2020, by List Industries, Inc., Deerfield Beach, Florida; Lyon LLC, Montgomery, Illinois; Penco Products, Inc., Greenville, North Carolina; and Tennsco Corp., Dickson, Tennessee.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.— In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission will not be conducting an in-person Title VII (antidumping and countervailing duty) preliminary staff conference at the Commission's headquarters. Information about the format of the conference on Thursday, July 30, 2020 will be provided separately. Requests to participate in the conference should be

emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before July 28, 2020. Please provide an email address for each conference participant in the email. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before August 4, 2020, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: July 9, 2020.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2020–15277 Filed 7–14–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1020 (Third Review)]

Barium Carbonate From China; Scheduling of an Expedited Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on barium carbonate from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: April 6, 2020.

FOR FURTHER INFORMATION CONTACT: Jason Duncan (202–205–3432), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On April 6, 2020, the Commission determined that the domestic interested party group response to its notice of institution (85 FR 125, January 2, 2020) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the review will be placed in the nonpublic record on July 13, 2020, and made available to persons on the Administrative Protective Order service list for this review. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before July 20, 2020 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by July 20, 2020. However, should the Department of Commerce (''Commerce'') extend the

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the response submitted by Chemical Products Corporation to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules with respect to filing were revised effective July 25, 2014. *See* 79 FR 35920 (June 25, 2014). The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: July 10, 2020.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2020–15269 Filed 7–14–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1153 (Second Review)]

Certain Tow-Behind Lawn Groomers and Parts Thereof From China

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on certain tow-behind lawn groomers and parts thereof from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2]

Background

The Commission instituted this review on January 2, 2020 (85 FR 117) and determined on April 6, 2020 that it would conduct an expedited review (85 FR 34464, June 4, 2020).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on July 9, 2020. The views of the Commission are contained in USITC Publication 5089 (July 2020), entitled *Certain Tow-Behind Lawn Groomers and Parts Thereof from China: Investigation No. 731–TA–1153 (Second Review).*

By order of the Commission.

Issued: July 9, 2020.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2020–15270 Filed 7–14–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Resource Conservation and Recovery Act and Other Statutes

On July 9, 2020, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Texas in the lawsuit entitled *United States and State of Texas* v. *E.I. DuPont De Nemours and Company, Case No. 4:20-cv-02423,* for violations of federal and state environmental laws during the production of agrichemicals at a manufacturing plant located in La Porte, Harris County, Texas.

The proposed Consent Decree resolves the claims of the United States and the State of Texas under (1) the Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.,* implementing regulations and the delegated program under the Texas Solid Waste Disposal Act (Texas Health and Safety Code ch. 361), (2) the Clean Air Act, 42 U.S.C. 7401 *et seq.,* implementing regulations, and Texas Clean Air Act (Tex. Health and Safety Code ch. 382), and (3) the Clean Water Act, 33 U.S.C. 1251, *et seq.,* implementing regulations, and the Texas Water Code ch. 26. The Consent Decree provides for payment of a civil penalty of $3,195,000 ($1,710,000 to the United States and $1,485,000 to the State of Texas), payment of attorneys' fees of $225,000 to the State of Texas, and performance of injunctive relief to resolve the violations alleged in the Complaint.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and State of Texas* v. *E.I. DuPont De Nemours and Company, Case No. 4:20–cv–02423,* D.J. Ref. No. 90–5–2–1–08181/3. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $10.75 (25 cents per page reproduction cost) for the Consent Decree or $14.00 (25 cents per page reproduction cost) for the Consent Decree and Appendices, payable to the United States Treasury.

Thomas Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–15296 Filed 7–14–20; 8:45 am]

BILLING CODE 4410–15–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner Amy A. Karpel did not participate in this vote.

DEPARTMENT OF JUSTICE

[OMB Number 1110–0071]

Agency Information Collection Activities; Proposed eCollection eComments Request; National Use-of-Force Data Collection: Extension of a Currently Approved Collection

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Federal Bureau of Investigation's (FBI's) Criminal Justice Information Services Division is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Comments are encouraged and will be accepted for 30 days until August 14, 2020.

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 FBI, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether, and if so, how the quality, utility, and clarity of the information to be collected can be enhanced; 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:* Extension of a currently approved collection.

(2) *The Title of the Form/Collection:* National Use-of-Force Data Collection.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is 1110–0071. Sponsor: Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Federal, state, local, and tribal law enforcement agencies.

Abstract: The FBI has a long-standing tradition of collecting data and providing statistics concerning Law Enforcement Officers Killed and Assaulted (LEOKA) and justifiable homicides. To provide a better understanding of the incidents of use of force by law enforcement, the Uniform Crime Reporting (UCR) Program developed a new data collection for law enforcement agencies to provide information on incidents where use of force by a law enforcement officer has led to the death or serious bodily injury of a person, as well as when a law enforcement officer discharges a firearm at or in the direction of a person.

When a use-of-force incident occurs, Federal, state, local, and tribal law enforcement agencies provide information to the data collection on characteristics of the incident, subjects of the use of force, and the officers who applied force in the incident. Agencies positively affirm, on a monthly basis, whether their agency did or did not have a use-of-force incident that resulted in a fatality, a serious bodily injury to a person, or a firearm discharge at or in the direction of a person. When no use-of-force incident occurs in a month, agencies submit a zero report. Enrollment information from agencies and state points of contact is collected when the agency or contact initiates participation in the data collection. Enrollment information is updated no less than annually to assist with managing this data.

The new data collection defines a law enforcement officer using the current LEOKA definition: ''All federal, state, county, and local law enforcement officers (such as municipal, county police officers, constables, state police, highway patrol, sheriffs, their deputies, federal law enforcement officers, marshals, special agents, etc.) who are sworn by their respective government authorities to uphold the law and to safeguard the rights, lives, and property of American citizens. They must have full arrest powers and be members of a public governmental law enforcement agency, paid from government funds set aside specifically for payment to sworn police law enforcement organized for the purposes of keeping order and for preventing and detecting crimes, and apprehending those responsible.''

The definition of ''serious bodily injury'' is based, in part, on Title 18 U.S.C., Section 2246(4), to mean ''bodily injury that involves a substantial risk of death, unconsciousness, protracted and obvious disfigurement, or protracted loss or impairment of the function of a bodily member, organ, or mental faculty.'' These actions include the use of a firearm; an electronic control weapon (*e.g.,* Taser); an explosive device; pepper or OC (oleoresin capsicum) spray or other chemical agent; a baton; an impact projectile; a blunt instrument; hands-fists-feet; or canine.

(5) *A total number of respondents and the amount of time estimated for an average respondent to respond:* As of June 2020, a total of 6,837 agencies covering 439,936 law enforcement officers were enrolled in the National Use-of-Force Data Collection. The burden hours per incident are estimated to be 0.63 of an hour for completion, around 38 minutes per incident.

(6) *An estimate of the total public burden (in hours) associated with the collection:* Burden estimates are based on sources from the FBI's UCR Program, the Bureau of Justice Statistics (BJS), and the Centers for Disease Control (CDC). The BJS recently estimated that approximately 1,400 fatalities attributed to a law enforcement use of force occur annually (Planty, et al., 2015, *Arrest-Related Deaths Program: Data Quality Profile, http://www.bjs.gov/index.cfm?ty=pbdetail&iid=5260*). In addition, the CDC estimates the incidences of fatal and nonfatal injury—including those due to legal intervention—from emergency department data. In their study, *The real risks during deadly police shootouts: Accuracy of the naïve shooter,* Lewinski, et al., (2015) estimate law enforcement officers miss their target approximately 50 percent of the time at the firing range. This information was used to develop a simple estimate for the number of times officers discharge a firearm at or in the direction of a person but do not strike the individual. In addition, the UCR Program collects counts of the number of sworn and civilian law enforcement employees in the nation's law enforcement agencies.

The following table shows burden estimates based on previous estimation criteria and current National Use-of-Force Data Collection enrollment numbers.

ESTIMATED BURDEN FOR ALL LAW ENFORCEMENT AGENCIES IN ANNUAL COLLECTION

Timeframe	Reporting Group	Approximate number of officers from participating agencies	Maximum per capita rate of use-of-force occurrence per officer	Minimum per capita rate of use-of-force occurrence per officer	Maximum estimated number of incidents	Minimum estimated number of incidents	Estimated burden hours per incident	Maximum estimate total number of burden hours	Minimum estimate total number of burden hours
Collection (Annual).	All agencies submitting data.	393,274	0.122	0.012	47,979	4,719	0.63	30,227	2,973

Based on previous estimation criteria and current enrollment numbers, the FBI is requesting 30,227 burden hours for the annual collection of this data.

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: July 10, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–15271 Filed 7–14–20; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJJDP) Docket No. 1780]

Notice of Charter Renewal of the Coordinating Council on Juvenile Justice and Delinquency Prevention

AGENCY: Coordinating Council on Juvenile Justice and Delinquency Prevention, Office of Justice Programs, Justice.

ACTION: Notice of charter renewal.

SUMMARY: Notice that the charter of the Coordinating Council on Juvenile Justice and Delinquency Prevention has been renewed.

FOR FURTHER INFORMATION CONTACT: Visit the website for the Coordinating Council at *www.juvenilecouncil.gov* or contact Elizabeth Wolfe, Designated Federal Official (DFO), Office of Juvenile Justice and Delinquency Prevention (OJJDP), by telephone at (202) 598–9310 (not a toll-free number) or via email: *elizabeth.wolfe@ojp.usdoj.gov*.

SUPPLEMENTARY INFORMATION: This **Federal Register** notice notifies the public that the Charter of the Coordinating Council on Juvenile Justice and Delinquency Prevention has been renewed in accordance with the Federal Advisory Committee Act, Section 14(a)(1). The renewal Charter was signed by U.S. Attorney General William P. Barr on June 29, 2020. One can obtain a copy of the renewal Charter by accessing the Coordinating Council on Juvenile Justice and Delinquency Prevention's website at *www.juvenilecouncil.gov*.

Catherine Doyle,

Associate Administrator, OJJDP.

[FR Doc. 2020–15195 Filed 7–14–20; 8:45 am]

BILLING CODE 4410–18–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2020–197 and CP2020–222; MC2020–198 and CP2020–223]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 17, 2020.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2020–197 and CP2020–222; *Filing Title:* USPS Request to Add Priority Mail Contract 638 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 9, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* July 17, 2020.

2. *Docket No(s).:* MC2020–198 and CP2020–223; *Filing Title:* USPS Request to Add Priority Mail Express & Priority Mail Contract 115 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 9, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* July 17, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–15267 Filed 7–14–20; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail and Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 15, 2020.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on June 24, 2020, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail & Parcel Select Contract 3 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–185, CP2020–209.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–14732 Filed 7–14–20; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89274; File No. SR–NYSEArca–2020–62]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees and Charges To Adopt Listing and Annual Fees for Actively Managed Proxy Shares Listed Under Rule 8.601–E and Managed Portfolio Shares Listed Under Rule 8.900–E

July 9, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on June 30, 2020, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, 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 Schedule of Fees and Charges to adopt listing and annual fees for Actively Managed Proxy Shares listed under Rule 8.601–E and Managed Portfolio Shares listed under Rule 8.900–E. 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 Schedule of Fees and Charges to adopt listing and annual fees for Actively Managed Proxy Shares listed under recently adopted Rule 8.601–E and Managed Portfolio Shares listed under Rule 8.900–E (collectively, ''Fund Shares'').

The proposed changes respond to the current extremely competitive environment for ETP listings in which issuers can readily favor competing venues or transfer their listings if they deem fee levels at a particular venue to be excessive, or discount opportunities available at other venues to be more favorable. As described below, the Exchange does not propose different pricing for Fund Shares. Rather, the Exchange proposes to incorporate Fund Shares into the existing listing and annual fees charged by the Exchange for Exchange Traded Products (''ETPs'').[4]

The proposed changes are designed to incentivize issuers to list new Fund Shares, transfer existing products to the Exchange, and maintain listings on the Exchange, which the Exchange believes will enhance competition both among issuers and listing venues, to the benefit of investors.

The Exchange proposes to implement the fee changes effective June 30, 2020.

Proposed Rule Change

On June 29, 2020, the Commission approved Rule 8.601–E regarding Exchange listing and trading of Active Proxy Portfolio Shares.[5] On April 15, 2020, the Commission issued a notice of filing and immediate effectiveness of the Exchange's proposed rule change to adopt NYSE Arca Rule 8.900–E regarding Exchange listing and trading of Managed Portfolio Shares.[6] In order

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] ''Exchange Traded Products'' are defined in footnote 3 of the current Schedule of Fees and Charges. The Exchange proposes to modify the definition to include Actively Managed Proxy Shares listed under Rule 8.601–E and Managed Portfolio Shares listed under Rule 8.900–E.

[5] *See* Securities Exchange Act Release No. 89185 (June 29, 2020) (SR–NYSEArca–2019–95).

[6] *See* Securities Exchange Act Release No. 88648 (April 15, 2020), 85 FR 22200 (April 21, 2020) (SR–NYSEArca–2020–32).

to specify pricing for Fund Shares, the Exchange proposes the following changes to the Schedule of Fees and Charges.

Listing Fees

Listing fees for ETPs are set forth in section 5.a of the Schedule of Fees and Charges. Currently, with the exception of various products defined as ''Generically-Listed Exchange Traded Products,'' the Exchange charges a $7,500 listing fee. The Exchange currently does not charge a listing fee for listing products pursuant to Rule 19b–4(e) under the Act if they satisfy all criteria—referred to as ''generic'' listing criteria—in the applicable Exchange ETP rule.[7]

The Exchange proposes to include Fund Shares in the definition of ''Exchange Traded Products'' in footnote 3 of the Schedule of Fees and Charges and as referenced in section 5.a thereto. Accordingly, because Fund Shares are not subject to Exchange listing pursuant to Rule 19b–4(e) under the Act and are not Generically-Listed Exchange Traded Products, Fund Shares will be subject to a listing fee of $7,500.

The Exchange believes that, for purposes of listing fees, it would be appropriate to treat Fund Shares like other Exchange Traded Products that are not ''Generically-Listed Exchange Traded Products'' and charge a listing fee of $7,500 because doing so would correlate the listing fee applicable to an issuer of ETPs to the resources required to list and maintain those ETPs on the Exchange. Specifically, Commentary .01 to Rule 8.601–E and Rule 8.900–E(b)(1) require that the Exchange file separate proposals under Section 19(b) of the Act before listing and trading a series of Active Proxy Portfolio Shares or Managed Portfolio Shares, respectively. As such, Fund Shares will require additional time and resources by Exchange staff to prepare and review rule filings and to communicate with issuers and Commission staff in connection therewith necessary for ETPs listed and traded pursuant to a rule change.

Annual Fees

Annual fees for ETPs are based on the number of shares outstanding per issuer.[8] Currently, as set forth in section 6.a of the Schedule of Fees and Charges, the Exchange charges the following annual fees for listed ETPs (including Exchange-Traded Fund Shares listed under Rule 5.2–E(j)(8) that track an Index), with the exception of Managed Fund Shares and Managed Trust Securities:

Number of shares outstanding (each issue)	Annual fee
Less than 25 million	$7,500
25 million up to 49,999,999	10,000
50 million up to 99,999,999	15,000
100 million up to 249,999,999	20,000
250 million up to 499,999,999	25,000
500 million and over	30,000

As set forth in section 6.b. of the Schedule of Fees and Charges, the Exchange charges the following annual fees for Managed Fund Shares, Managed Trust Securities and Exchange-Traded Fund Shares listed under Rule 5.2–E(j)(8) that do not track an Index:

Number of shares outstanding (each issue)	Annual fee
Less than 25 million	$10,000
25 million up to 49,999,999	12,500
50 million up to 99,999,999	20,000
100 million up to 249,999,999	25,000
250 million and over	30,000

The Exchange proposes to charge annual fees for Fund Shares that track how the Exchange currently charges annual fees for Managed Fund Shares, Managed Trust Securities and Exchange-Traded Fund Shares listed under Rule 5.2–E(j)(8) that do not track an Index. Accordingly, because Fund Shares, under the current Exchange listing rules, are more akin to Managed Fund Shares and Exchange-Traded Fund Shares that do not track an Index, the Exchange proposes to charge the annual fees set forth in section 6.b of the Schedule of Fees and Charges.

The Exchange believes that charging Fund Shares the same current annual fees applicable to Managed Fund Shares, Managed Trust Securities and Exchange-Traded Fund Shares that do not track an Index would be appropriate because those relatively higher annual fees (compared to ''Generically-Listed Exchange Traded Products'') better correlate with higher Exchange costs associated with similar actively managed products such as Managed Fund Shares, Managed Trust Securities, and Exchange-Traded Fund Shares that do not track an Index, including costs related to issuer services, listing administration, product development and regulatory oversight.

Finally, as noted above, the Exchange proposes to add Fund Shares to current footnote 3 which defines the term ''Exchange Traded Products'' for purposes of the Schedule of Fees and Charges.

Each of the proposed changes described above is not otherwise intended to address other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[10] 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 Change Is Reasonable

As discussed above, the Exchange operates in a highly competitive market for the listing of ETPs. Specifically, ETP issuers can readily favor competing venues or transfer listings if they deem fee levels at a particular venue to be excessive, or discount opportunities available at other venues to be more favorable. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [11]

The Exchange believes that the ongoing competition among the exchanges with respect to new listings and the transfer of existing listings among competitor exchanges demonstrates that issuers can choose different listing markets in response to fee changes. Accordingly, competitive

[7] The Schedule of Fees and Charges refers to these as ''Generically-Listed Exchange Traded Products.'' ''Generically-Listed Exchange Traded Products'' currently include Investment Company Units, Portfolio Depositary Receipts, Managed Fund Shares, Exchange-Traded Fund Shares listed under Rule 5.2–E(j)(8), and Currency Trust Shares that are listed on the Exchange pursuant to Rule 19b–4(e) under the Act, and for which a proposed rule change pursuant to Section 19(b) of the Act is not required to be filed with the Commission.

[8] Annual fees are assessed each January in the first full calendar year following the year of listing. The aggregate total shares outstanding is calculated based on the total shares outstanding as reported by the fund issuer or fund ''family'' in its most recent periodic filing with the Commission or other publicly available information. Annual fees apply regardless of whether any of these funds are listed elsewhere.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) & (5).

[11] *See* Regulation NMS, 70 FR at 37499.

forces constrain exchange listing and annual fees. Stated otherwise, changes to exchange listing and annual fees can have a direct effect on the ability of an exchange to compete for new listings.

Given this competitive environment, the proposal represents a reasonable attempt to establish pricing for ETPs listed under Rule 8.601–E and Rule 8.900–E.

The Exchange currently does not charge listing fees for ETPs that satisfy generic listing criteria set forth in its rules. Products that list without a rule filing do not entail the additional time and resources required for ETPs that require a rule filing. However, as noted above, Commentary .01 to Rule 8.601–E and Rule 8.900–E (b)(1) require that the Exchange file separate proposals under Section 19(b) of the Act before listing and trading a series of Active Proxy Portfolio Shares or Managed Portfolio Shares, respectively. As such, in contrast to ETPs for which the Exchange is not required to file a proposal under Section 19(b) of the Act, the listing and trading of Fund Shares will require additional time and resources by Exchange staff to prepare and review rule filings and to communicate with issuers and Commission staff in connection therewith necessary for Fund Shares listed and traded pursuant to a rule change. Accordingly, the Exchange believes the $7,500 listing fee proposed for Fund Shares is reasonable in that it is the same as the listing fee for other ETPs that are not ''Generically-Listed Exchange Traded Products.''

Annual fees for ETPs are based on the number of shares outstanding per issuer, and then are further differentiated based on whether the ETP is index based or not, with higher annual fees for ETPs that are not based on an index. The Exchange believes that it is reasonable to charge annual fees for Fund Shares based on that same differentiation. The Exchange believes that charging Fund Shares the current annual fees applicable to Managed Fund Shares and Managed Trust Securities, which are also actively managed products, as well as Exchange-Traded Fund Shares that do not track an index, would be reasonable because those annual fees better correlate with the higher Exchange costs for listing and trading Fund Shares, including costs related to issuer services, listing administration, product development and regulatory oversight.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes its proposal equitably allocates its fees among its market participants. In the prevailing competitive environment, issuers can readily favor competing venues or transfer listings if they deem fee levels at a particular venue to be excessive, or discount opportunities available at other venues to be more favorable.

The Exchange believes that, for purposes of listing fees, it would be appropriate to treat Fund Shares like other Exchange Traded Products that are not ''Generically-Listed Exchange Traded Products'' and charge a listing fee of $7,500 because doing so would correlate the listing fee applicable to an issuer of ETPs to the resources required to list and maintain those ETPs on the Exchange. Fund Shares will incur additional time and resources required by Exchange staff to prepare and review rule filings and to communicate with issuers and Commission staff in connection therewith necessary for ETPs listed and traded pursuant to a rule change.

The proposed annual fees for Fund Shares are equitable because the proposed increased annual fees would apply uniformly to all issuers. Moreover, the proposed fees would be equitably allocated among issuers because issuers would continue to qualify for the annual fee based on the number of shares outstanding and under criteria applied uniformly to all such issuers.

The proposal neither targets nor will it have a disparate impact on any particular category of market participant. The proposed listing and annual fees would be applicable to all existing and potential issuers of Fund Shares uniformly and in equal measure.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, issuers are free to list elsewhere if they believe that alternative venues offer them better value.

The Exchange believes it is not unfairly discriminatory to apply to Fund Shares the same fees applicable to Managed Fund Shares, Managed Trust Securities and Exchange-Traded Fund Shares that do not track an index because the proposed fees would be offered on an equal basis to all issuers listing Fund Shares on the Exchange. Moreover, the proposed listing and annual fees for Fund Shares would apply to issuers in the same manner as the current listing and annual fees for ETPs, including Managed Fund Shares, Managed Trust Securities and Exchange-Traded Fund Shares that do not track an index.

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,[12] the Exchange believes that the proposed rule change would not 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 competition because it would establish listing and annual fees for Fund Shares, thereby encouraging issuers to develop and list additional products on the Exchange that the Exchange believes will enhance competition both among issuers and listing venues, to the benefit of investors. The proposal also ensures that the fees charged by the Exchange accurately reflect the services provided and benefits realized by listed issuers. The market for listing services is extremely competitive. Issuers have the option to list their securities on these alternative venues based on the fees charged and the value provided by each listing exchange. Because issuers have a choice to list their securities on a different national securities exchange, the Exchange does not believe that the proposed fee changes impose a burden on competition.

Intramarket Competition. The proposed changes are designed to attract additional listings to the Exchange by establishing listing and annual fees for ETPs listed under new rules. The Exchange believes that the proposed changes would continue to incentivize issuers to develop and list new products, transfer existing products to the Exchange, and maintain listings on the Exchange. The proposed fees would apply to all issuers equally, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive listings market in which issuers can readily choose alternative listing venues. In such an environment, the Exchange must adjust its fees and discounts to remain competitive with other exchanges competing for the same listings. Because competitors are free to

[12] 15 U.S.C. 78f(b)(8).

modify their own fees and discounts in response, and because issuers may readily adjust their listing decisions and practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition. As such, the proposal is a competitive proposal designed to enhance pricing competition among listing venues and implement pricing for Fund Shares to reflect the revenue and expenses associated with listing on the Exchange.

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) [13] of the Act and subparagraph (f)(2) of Rule 19b–4 [14] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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) [15] 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–NYSEArca–2020–62 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2020–62. 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–NYSEArca–2020–62 and should be submitted on or before August 5, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15211 Filed 7–14–20; 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] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89279; File No. SR–NYSEArca–2020–48]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade Shares of Gabelli ETFs Under Rule 8.900–E, Managed Portfolio Shares

July 9, 2020.

On May 15, 2020, NYSE Arca, Inc. filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the following under Rule 8.900–E (Managed Portfolio Shares): Gabelli Growth Innovators ETF, Gabelli Financial Services ETF, Gabelli Small Cap Growth ETF, Gabelli Small & Mid Cap ETF, Gabelli Micro Cap ETF, Gabelli ESG ETF, Gabelli Asset ETF, Gabelli Equity Income ETF, and Gabelli Green Energy ETF. The proposed rule change was published for comment in the **Federal Register** on June 3, 2020.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is July 18, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates September 1, 2020 as the date by which the Commission shall

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 88970 (May 28, 2020), 85 FR 34262.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2020–48).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15212 Filed 7–14–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33923; File No. 812–15093]

J.P. Morgan Exchange-Traded Fund Trust, et al.

July 10, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), and 22(d) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act.

Applicants: J.P. Morgan Exchange-Traded Fund Trust (the ''Trust''), J.P. Morgan Investment Management Inc. (the ''Adviser'') and JPMorgan Distribution Services, Inc. (the ''Distributor'').

Summary of Application: Applicants request an order (''Order'') that permits: (a) ActiveShares ETFs (as described in the Reference Order (as defined below)) to issue shares (''Shares'') redeemable in large aggregations only (''creation units''); (b) secondary market transactions in Shares to occur at negotiated market prices rather than at net asset value; (c) certain affiliated persons of an ActiveShares ETF to deposit securities into, and receive securities from, the ActiveShares ETF in connection with the purchase and redemption of creation units; and (d) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the ActiveShares ETFs to acquire Shares of the ActiveShares ETFs. The Order would incorporate by reference terms and conditions of a previous order granting the same relief sought by applicants, as that order may be amended from time to time (''Reference Order'').[1]

Filing Date: The application was filed on February 3, 2020.

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 by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on August 4, 2020, 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 at *Secretarys-Office@sec.gov.*

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, *Secretarys-Office@sec.gov.* Applicants: Gregory S. Samuels, J.P. Morgan Investment Management Inc., *gregory.s.samuels@jpmchase.com;* Elizabeth A. Davin, J.P. Morgan Investment Management Inc., *elizabeth.a.davin@jpmorgan.com;* and Allison M. Fumai, Dechert LLP, *allison.fumai@dechert.com.*

FOR FURTHER INFORMATION CONTACT: Laura J. Riegel, Senior Counsel, at (202) 551–3038 or Trace W. Rakestraw, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants

1. The Trust is a statutory trust organized under the laws of the State of Delaware and will consist of one or more series operating as ActiveShares ETFs. The Trust is registered as an open-end management investment company under the Act. Applicants seek relief with respect to one fund (the ''Initial Fund'') and Funds (as defined below). The Funds will operate as ActiveShares ETFs as described in the Reference Order.[2]

2. The Adviser, a Delaware corporation, will be the investment adviser to the Initial Fund. An Adviser (as defined below) will serve as investment adviser to each Fund. The Adviser is, and any other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). The Adviser may enter into sub-advisory agreements with other investment advisers to act as sub-advisers with respect to the Funds (each a ''Sub-Adviser''). Any Sub-Adviser will be registered under the Advisers Act.

3. The Distributor is a Delaware corporation and a broker-dealer registered under the Securities Exchange Act of 1934, as amended, and will act as the principal underwriter of Shares of the Funds. Applicants request that the requested relief apply to any distributor of Shares, whether affiliated or unaffiliated with the Adviser and/or Sub-Adviser (included in the term ''Distributor''). Any Distributor will comply with the terms and conditions of the Order.

Applicants' Requested Exemptive Relief

4. Applicants seek the requested Order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), and 22(d) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested Order would permit applicants to offer ActiveShares ETFs. Because the relief requested is the same as the relief granted by the Commission under the Reference Order and because the Adviser has entered into a licensing agreement with Precidian Funds LLC in order to offer ActiveShares ETFs,[3] the Order would incorporate by reference the terms and conditions of the Reference Order.

5. Applicants request that the Order apply to the Initial Fund and to any other existing or future open-end

[6] 17 CFR 200.30–3(a)(31).

[1] Precidian ETFs Trust, *et al.,* Investment Company Act Release Nos. 33440 (April 8, 2019) (notice) and 33477 (May 20, 2019) (order).

[2] To facilitate arbitrage, an ActiveShares ETF disseminates a ''verified intraday indicative value'' or ''VIIV,'' reflecting the value of its portfolio holdings, calculated every second during the trading day. To protect the identity and weightings of its portfolio holdings, an ActiveShares ETF sells and redeems its Shares in creation units to authorized participants only through an unaffiliated broker-dealer acting on an agency basis.

[3] Aspects of the Funds are covered by intellectual property rights, including but not limited to those which are described in one or more patent applications.

management investment company or series thereof that: (a) Is advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser (any such entity included in the term ''Adviser''); (b) operates as an ActiveShares ETF as described in the Reference Order; and (c) complies with the terms and conditions of the Order and of the Reference Order, which is incorporated by reference into the Order (each such company or series and the Initial Fund, a ''Fund'').[4]

6. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Applicants submit that for the reasons stated in the Reference Order the requested relief meets the exemptive standards under sections 6(c), 17(b) and 12(d)(1)(J) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15290 Filed 7–14–20; 8:45 am]

BILLING CODE 8011–01–P

[4] All entities that currently intend to rely on the Order are named as applicants. Any other entity that relies on the Order in the future will comply with the terms and conditions of the Order and of the Reference Order, which is incorporated by reference into the Order.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89270; File No. SR–FICC–2020–007]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Clearing Agency Risk Management Framework

July 9, 2020.

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 July 7, 2020, Fixed Income Clearing Corporation (''FICC'') 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 clearing agency. FICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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 proposed rule change consists of amendments to the Clearing Agency Risk Management Framework (''Risk Management Framework'' or ''Framework'') of FICC and its affiliates, National Securities Clearing Corporation (''NSCC'') and The Depository Trust Company (''DTC,'' and together with NSCC and FICC, the ''Clearing Agencies''). Specifically, the proposed rule change would (1) include a description of a set of policies that addresses the Clearing Agencies' compliance with Rule 17Ad–22(e)(22) of the Standards for Covered Clearing Agencies (''Standards''), under the Act,[5] (2) update the Risk Management Framework to reflect recent changes to certain processes and other matters described in the Framework, and changes to the status of documents identified in the Framework; and (3) clarify the descriptions of certain matters within the Framework to improve comprehensiveness and correct errors, as further described below.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] 17 CFR 240.17Ad–22(e)(22).

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency 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

1. Purpose

The Clearing Agencies adopted the Risk Management Framework[6] to provide an outline for how each of the Clearing Agencies (i) maintains a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities; (ii) comprehensively manages legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by it; (iii) identifies, monitors, and manages risks related to links it establishes with one or more clearing agencies, financial market utilities, or trading markets; and (iv) meets the requirements of its participants and the markets it serves efficiently and effectively. In this way, the Risk Management Framework currently supports the Clearing Agencies' compliance with Rules 17Ad–22(e)(1), (3), (20) and (21) of the Standards,[7] as described in the Initial Filing. In addition to setting forth the manner in which each of the Clearing Agencies addresses these requirements, the Risk Management Framework also contains a section titled ''Framework Ownership and Change Management'' that, among other matters, describes the Framework ownership and the required governance process for review and approval of changes to the Framework. In connection with the annual review and approval of the Framework by the Board of Directors of each of NSCC, DTC and FICC (each a ''Board'' and collectively, the ''Boards''), the Clearing Agencies are proposing to make certain revisions to the Framework.

The proposed changes would add a new Section 4.4 to describe a policy and a communication standard document

[6] *See* Securities Exchange Act Release No. 81635 (September 15, 2017), 82 FR 44224 (September 21, 2017) (SR–DTC–2017–013; SR–NSCC–2017–012; SR–FICC–2017–016) (''Initial Filing'').

[7] 17 CFR 240.17Ad–22(e)(1), (3), (20) and (21).

that support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22), which requires the Clearing Agencies to establish, implement, maintain and enforce written policies and procedures reasonably designed to use, or at a minimum accommodate, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing, and settlement.[8]

The proposed changes would also update the Risk Management Framework to reflect (1) a change to the name of the Vendor Risk Management group to the Third Party Risk Management group; (2) a change to the format of the Balanced Business Scorecard, which is an internal performance management tool used to measure the effectiveness of various aspects of the operations of The Depository Trust & Clearing Corporation (''DTCC'') and its subsidiaries, including the Clearing Agencies; and (3) the filing of certain documents identified in the Framework, pursuant to Section 19(b)(1) of the Act,[9] and the rules thereunder, and Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled the Payment, Clearing, and Settlement Supervision Act of 2010,[10] and the rules thereunder (collectively, ''Filing Requirements''), as described in greater detail below.

The proposed changes would also clarify and enhance the descriptions in the Risk Management Framework to (1) identify the requirement of Rule 17Ad–22(e)(3)(i) under the Act that the Framework be reviewed and approved by the Boards on an annual basis; [11] (2) identify the role of the DTCC Legal Department in supporting the management of legal risks that arise in or are borne by the Clearing Agencies; (3) enhance the description of the DTCC Risk Department as ''Second Line of Defense,'' (4) enhance the description of the DTCC Internal Audit Department as ''Third Line of Defense;'' (5) enhance the description of a policy relating to the establishment and governance of internal management committees; (6) enhance the description of the processes designed to maintain comprehensive policies, procedures and other documents; (7) clarify that certain activities described in the Framework that relate to the public disclosure of material information, including market data, address the Clearing Agencies' compliance with Rule 17Ad–22(e)(23) under the Act; [12] (8) enhance the description of the management of systemic risks by describing the role of the Systemic Risk Council; (9) correct a sentence by removing an unnecessary phrase; and (10) enhance the descriptions of certain actions by removing the indication that the Clearing Agencies have discretion in engaging in those actions.

Finally, the proposed changes would correct an error in the Risk Management Framework to identify the Audit Committees of the Boards as the committees to which the DTCC Internal Audit Department has a direct reporting line. Each of these proposed changes is described below.

i. Proposed Amendments To Describe Policies That Address Compliance With Rule 17Ad–22(e)(22)

First, the proposed changes would add a new Section 4.4 to the Framework to describe a policy maintained by the Clearing Agencies to use and accommodate relevant internationally accepted communication procedures and standards to facilitate efficient payment, clearing, and settlement, to support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22).[13]

The policy describes how the communication standards and data formats that are currently used by the Clearing Agencies for payment, clearing, and settlement are regarded as accepted industry standards for transactions processed through the Clearing Agencies. The policy also provides that the Clearing Agencies would accommodate new industry standards that are considered internationally accepted communication procedures and standards. The new Section 4.4 would also state that the Clearing Agencies maintain a communication standard document that supports this policy.

The Clearing Agencies are proposing to amend the Risk Management Framework to adopt a new Section 4.4 that would describe these documents, which support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22).[14]

ii. Proposed Amendments To Update the Framework

Second, the proposed changes would update the Risk Management Framework to reflect recent developments with respect to certain processes and other matters described in the Framework, and changes to the status of documents described in the Framework, as described below.

1. Proposed Change To Identify Third Party Risk Management

Section 4 of the Risk Management Framework outlines ways in which each of the Clearing Agencies manages certain risks that arise in or are borne by it. Specifically, Section 4.2 describes the management of risks related to material interdependencies and external links that may be established by the Clearing Agencies. The Clearing Agencies represent that management of risks presented by vendors and other material service providers is guided by a function within the Operational Risk Management group within the Group Chief Risk Office. This function was previously referred to as ''Vendor Risk Management.'' While the role and responsibilities of this risk management function have not changed, its name has recently been changed to ''Third Party Risk Management'' to clarify that the function covers any material third party service provider that provides a service to a DTCC entity.

The Clearing Agencies are proposing to amend Section 4.2.1 of the Risk Management Framework to reflect this name change and to clarify that the function covers any material third party service provider that provides a service to a DTCC entity by adding ''Third Party'' as a new defined term. The Clearing Agencies are also proposing to identify the existing policy and procedure that is maintained to manage these risks.

2. Proposed Change to Description of Balanced Business Scorecard

Section 4.3 of the Risk Management Framework addresses certain processes implemented by the Clearing Agencies in order to be efficient and effective in meeting the requirements of their respective participants and the markets they serve.[15] One of the methods the Clearing Agencies use to meet these requirements is the periodic creation of a Balanced Business Scorecard, which provides insight into the effectiveness of the Clearing Agencies' operations, information technology service levels, financial performance, human capital, and their respective participants' experience.

Previously, a Balanced Business Scorecard (referred to as the ''Core Balance Business Scorecard'') was created for the Clearing Agencies, and a separate Balanced Business Scorecard

[8] 17 CFR 240.17Ad–22(e)(22).

[9] 15 U.S.C. 78s(b)(1).

[10] 12 U.S.C. 5465(e)(1).

[11] 17 CFR 240.17Ad–22(e)(3)(i).

[12] 17 CFR 240.17Ad–22(e)(23).

[13] 17 CFR 240.17Ad–22(e)(22).

[14] *Id.*

[15] Such processes support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(21) under the Act. 17 CFR 240.17Ad–22(e)(21).

was created for the other subsidiaries of DTCC. Recently, these two tools merged, and only one Balanced Business Scorecard (now referred to as the ''DTCC Balanced Business Scorecard'') is created, which addresses DTCC and each of its subsidiaries, including each of the Clearing Agencies. While the new, enterprise-wide Balanced Business Scorecard reports its conclusions on a less granular, enterprise-wide basis, it is created using the same set of metrics as the legacy Clearing Agencies version. Therefore, the Balanced Business Scorecard continues to support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(21) under the Act.[16] The Balanced Business Scorecard now reports those metrics in the context of the DTCC enterprise, at a less granular level.

The Clearing Agencies are proposing to amend Section 4.3 of the Risk Management Framework to reflect the change in format of the Balanced Business Scorecard described above.

3. Proposed Change to Description of Certain Documents To Reflect Filing Pursuant to Filing Requirements

Following the adoption of the Risk Management Framework, certain documents that are identified in the Framework were filed pursuant to the Filing Requirements. The Clearing Agencies are proposing to revise the descriptions of these documents to reflect this change.

Section 3.3 of the Framework describes certain frameworks that are maintained by the Clearing Agencies and provide an outline for certain policies and procedures that address, in whole or in part, the management of operational, liquidity, credit, market, collateral, and other risks. This section identified five such frameworks, the Clearing Agency Operational Risk Management Framework, the Clearing Agency Liquidity Risk Management Framework, the Clearing Agency Securities Valuation Framework, the Clearing Agency Stress Testing Framework, and the Clearing Agency Model Risk Management Framework. Each of these frameworks has been filed pursuant to the applicable Filing Requirements and adopted by the Clearing Agencies.[17] The Clearing Agencies are proposing to update Section 3.3 to reflect this change.

Section 5 of the Risk Management Framework describes the plans that are maintained by each of the Clearing Agencies for their recovery or orderly wind-down (''R&W Plans''). The R&W Plans were still in development when the Framework was adopted, but have since been finalized, approved by the Boards, filed pursuant to the Filing Requirements, and adopted by the Clearing Agencies.[18] Therefore, the Clearing Agencies are proposing to update Section 5 to reflect these developments, and to describe the ongoing governance of the R&W Plans.

iii. Proposed Amendments To Clarify, Enhance, and Correct Descriptions in the Framework

Finally, the proposed changes would enhance the descriptions of certain matters within the Risk Management Framework to improve its clarity and comprehensiveness and correct an error, as described below.

1. Proposed Change To Correct Annual Approval of Framework by Boards

Section 2 of the Risk Management Framework addresses the Framework's ownership and change management. This section currently states that the Framework should be reviewed by the document owner no less frequently than annually but does not specifically identify the requirement that the Framework also be approved by the Boards on an annual basis. The Clearing Agencies are proposing to correct the Framework to include the requirement that the Framework be approved by the Boards, or a duly authorized committee of the Boards, annually.

Rule 17Ad–22(e)(3) under the Act requires that the Clearing Agencies maintain a sound risk management framework for comprehensively managing the risks that arise in or are borne by the Clearing Agencies, including investment and custody risks.[19] Rule 17Ad–22(e)(3)(i) under the Act requires that the risk management policies, procedures, and systems that are maintained in compliance with Rule 17Ad–22(e)(3) be subject to review on a specified periodic basis and be approved by the Boards annually.[20] As stated above, the Framework provides an outline for how each of the Clearing Agencies comprehensively manages legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by it, as required by Rule 17Ad–22(e)(3) under the Act.[21] Therefore, the Risk Management Framework is reviewed and approved by the Boards annually, as required by Rule 17Ad–22(e)(3)(i) under the Act.[22]

The Clearing Agencies are proposing to amend Section 2 of the Framework to state that the Framework shall be approved by the Boards, or a duly authorized committee of the Boards, annually. The proposed change would correct the Framework to include this requirement, which is aligned with the applicable requirements of Rule 17Ad–22(e)(3)(i) under the Act.[23]

2. Proposed Change To Identify DTCC Legal Department's Role in Management of Clearing Agencies' Legal Risks

Section 3.1 of the Risk Management Framework describes the ''three lines of defense'' approach adopted by each of the Clearing Agencies for identifying, assessing, measuring, monitoring, mitigating, and reporting the risks that arise in or are borne by it. Currently, this section outlines the role of each line of defense, and specifically describes the roles of the DTCC Risk Department (''Risk Department'') and DTCC Internal Audit Department (''Internal Audit'') within this risk management approach. The DTCC Legal Department (''Legal Department'') also plays a particular role in the three lines of defense approach by supporting each line of defense in the management of legal risks.

While the Legal Department is currently identified as part of the control functions that form the second line of defense in Section 3.1.2, its particular role is not separately described. Therefore, the Clearing Agencies are proposing to update the introduction of Section 3.1 to state that the Legal Department supports each line of defense in the management of legal risks. This proposed change would more

[16] *Id.*

[17] *See* Securities Exchange Act Release Nos. 81745 (September 28, 2017), 82 FR 46332 (October 4, 2017) (SR–DTC–2017–014; SR–NSCC–2017–013; SR–FICC–2017–017) (Operational Risk Management Framework); 82377 (December 21, 2017), 82 FR 61617 (December 28, 2017) (SR–DTC–2017–004; SR–NSCC–2017–005; SR–FICC–2017–008) (Liquidity Risk Management Framework); 82006 (November 2, 2017), 82 FR 51892 (November 8, 2017) (SR–DTC–2017–016; SR–NSCC–2017–016; SR–FICC–2017–020) (Securities Valuation Framework); 82368 (December 19, 2017), 82 FR 61082 (December 26, 2017) (SR–DTC–2017–005; SR–FICC–2017–009; SR–NSCC–2017–006) (Stress Testing Framework); and 81485 (August 25, 2017), 82 FR 41433 (August 31, 2017) (SR–DTC–2017–008; SR–FICC–2017–014; SR–NSCC–2017–008) (Model Risk Management Framework).

[18] *See* Securities Exchange Act Release Nos. 83972 (August 28, 2018), 83 FR 44964 (September 4, 2018) (SR–DTC–2017–021); 83953 (August 27, 2018), 83 FR 44381 (August 30, 2018) (SR–DTC–2017–803); 83974 (August 28, 2018), 83 FR 44988 (September 4, 2018) (SR–NSCC–2017–017); 83955 (August 27, 2018), 83 FR 44340 (August 30, 2018) (SR–NSCC–2017–805); 83973 (August 28, 2018), 83 FR 44942 (September 4, 2018) (SR–FICC–2017–021); 83954 (August 27, 2018), 83 FR 44361 (August 30, 2018) (SR–FICC–2017–805).

[19] 17 CFR 240.17Ad–22(e)(3).

[20] 17 CFR 240.17Ad–22(e)(3)(i).

[21] 17 CFR 240.17Ad–22(e)(3).

[22] 17 CFR 240.17Ad–22(e)(3)(i).

[23] *Id.*

clearly describe the particular role of the Legal Department in this risk management approach.

3. Proposed Change To Enhance Description of DTCC's Risk Department as ''Second Line of Defense'' in Risk Management

As stated above, Section 3.1 of the Risk Management Framework describes the ''three lines of defense'' approach to risk management adopted by the Clearing Agencies. Section 3.1.2 describes the particular role of the Risk Department as the second line of defense within this risk management approach. The Clearing Agencies are proposing to amend this Section 3.1.2 to enhance the description of the Risk Department's role, including by providing details relating to the role of the Operational Risk Management group within the Risk Department. The proposed amendments would describe how the Operational Risk Management group addresses and escalates incidents based on a risk rating of those incidents. In addition, the proposed change would clarify the description relating to the procedures, processes, tools, mechanisms, analyses, and testing controls employed by the Risk Department and indicate that such procedures, etc. are subject to the parameters set forth in Section 3.3, which discusses the Filing Requirements and document standards relating to policies, procedures, frameworks and certain related documents. In addition, the Clearing Agencies are proposing to add a defined term in Section 3.1 to reflect that the Risk Department refers to the Risk Department of DTCC. The proposed changes would more clearly describe the particular role of the Risk Department in this risk management approach.

4. Proposed Change To Enhance Description of DTCC's Internal Audit Department as ''Third Line of Defense'' in Risk Management

Section 3.1.3 of the Risk Management Framework describes the particular role of Internal Audit as the third line of defense within the risk management approach. The Clearing Agencies are proposing to amend this Section 3.1.3 to enhance the description of Internal Audit's role, including by providing a clearer description of the responsibilities of Internal Audit, making grammatical changes to certain descriptions to improve readability, and removing references to Internal Audit as providing an advisory role to the Clearing Agencies. By removing references to advisory services, the proposed changes would conform the Risk Management Framework to the charter of the Audit Committees of the Boards, where similar changes have been made to reinforce the group's role as the third line of defense in risk management and its independence and objectivity in the performance of assurance services. In addition, the Clearing Agencies are proposing to add a defined term in Section 3.1 to clarify that Internal Audit refers to the Internal Audit Department of DTCC.

5. Proposed Change To Enhance Description of Policy Regarding Management Committees and Oversight

Section 3.2 of the Risk Management Framework states that a set of senior management committees provides oversight of various aspects of the Clearing Agencies' activities, including risk management, and describes the policy that sets forth the requirements for establishing and governing these committees. The Clearing Agencies are proposing to amend Section 3.2 by including a reference to the described document and providing a clearer and more complete description of the contents of this policy and the ongoing governance requirements of senior management committees. The proposed changes would not make any substantive changes to this description.

6. Proposed Change To Enhance Description of Management of Policies, Procedures, and Other Documents

Section 3.3.1 of the Risk Management Framework states that the Clearing Agencies maintain comprehensive policies and procedures designed to identify, measure, monitor and manage the risks that arise in or are borne by the Clearing Agencies, and describes a set of standards the Clearing Agencies have established for creating and managing these documents. The Clearing Agencies are proposing to amend the description of these standards. The proposed amendments to Section 3.3.1 would re-word the descriptions of these standards by, for example, more clearly describing the governance of these documents, how these standards provide guidance on reviews of these documents by document owners, and the role of the document owners in adhering to these standards. The proposed changes would not make any substantive changes to this description.

7. Proposed Change To Clarify Regulatory Basis of Certain Public Disclosures

Section 4.1 of the Risk Management Framework states that the Clearing Agencies provide their respective participants with information and incentives to enable them, and, through them, their customers, to understand, monitor, manage, and contain the risks they pose to the respective Clearing Agencies, and identifies some of the tools the Clearing Agencies provide to their participants to facilitate this understanding. The Clearing Agencies are proposing to amend Section 4.1 to make clarifying edits.

First, the proposed amendments would clarify that the tools and activities described in Section 4.1 support the Clearing Agencies' compliance with Rule 17Ad–22(e)(23) under the Act.[24] Rule 17Ad–22(e)(23) requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for publicly disclosing relevant basic data on transaction volume and values, and a comprehensive public disclosure that describes their material rules, policies, and procedures regarding their legal, governance, risk management, and operating framework, accurate in all material respects at the time of publication.[25] Certain matters described in Section 4.1 of the Framework, including the publication of disclosure frameworks and quantitative disclosures (described below), support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(23).[26] Therefore, the Clearing Agencies would update the introduction to Section 4.1, and make a conforming change to Section 1 of the Framework, to refer to Rule 17Ad–22(e)(23).[27]

Second, the proposed amendments would correct a statement in Section 4.1 of the Framework regarding the disclosure frameworks posted to the DTCC website for each of the Clearing Agencies on a biennial basis, which provide a comprehensive description of how the businesses and operations of the Clearing Agencies reflect the Principles for financial market infrastructures, issued by the Committee on Payment and Settlement Systems (''CPSS'') and the Technical Committee of the International Organization of Securities Commissions (''IOSCO'').[28] These disclosure frameworks also address how the businesses and operations of the Clearing Agencies

[24] 17 CFR 240.17Ad–22(e)(23).

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] CPSS and the Technical Committee of IOSCO, Principles for financial market infrastructures (April 16, 2012), *available at http://www.bis.org/cpmi/publ/d101a.pdf.* In 2014, CPSS became the Committee on Payments and Market Infrastructures (''CPMI'').

reflect the Standards. Therefore, the Clearing Agencies would correct this statement in Section 4.1 regarding the scope of the disclosure frameworks by also referring to the Standards.

Finally, the proposed amendments would correct a statement in Section 4.1 of the Framework regarding the quantitative disclosures that are posted to the DTCC website on a quarterly basis, which disclose certain quantitative data and other information as set out in the Public quantitative disclosure standards for central counterparties published by CPMI and IOSCO.[29] Currently, Section 4.1 states that these disclosures relate to the Clearing Agencies. However, these disclosures are only required for central counterparties and, as such, only relate to NSCC and FICC, and not DTC. The Clearing Agencies would correct this error by replacing ''Clearing Agencies'' with ''NSCC and FICC, as central counterparties'' in Section 4.1 of the Framework.

8. Proposed Change To Enhance Description of Governance of Systemic Risk Management

The proposed change would enhance the description of the governance of systemic risk management in Section 4.2.1 by including a description of the Systemic Risk Council, the frequency of this Council's meetings, and stating that matters discussed at these meetings may be escalated to the Management Risk Committee or the Board Risk Committee when appropriate. The proposed changes would improve the descriptions in the Framework by providing additional details regarding the governance of systemic risk management.

9. Proposed Change To Enhance Description of Management of Risk Related to Other External Links

The proposed change would enhance the description of the management of risks related to external links in Section 4.2.2 by identifying a policy and a procedure that are maintained by the Clearing Agencies to govern this process. The proposed change would improve the disclosures in the Framework by providing a clear reference to these documents.

10. Proposed Change To Remove Unnecessary Phrase

The proposed change would remove an unnecessary phrase '', is set forth in'' that is incorrectly at the end of a sentence in Section 1 of the Framework.

11. Proposed Change To Rephrase Sentences That Incorrectly Indicate Discretion in Taking Certain Actions

The proposed change would rephrase four sentences in the Framework that currently indicate the action described is discretionary. First, the proposed change would rephrase a statement in Section 4.2.1 to remove the indication that the Clearing Agencies have discretion to not manage risks related to participants and settlement banks. Second, the proposed change would rephrase a statement in Section 4.2.1 to remove the indication that the Clearing Agencies have discretion to not maintain policies, procedures or templates relating to the management of third-party risks. Third, the proposed change would rephrase a statement in Section 4.2.2 to remove the indication that the General Counsel's Office has discretion in reviewing certain key link arrangements. Finally, the proposed change would rephrase a statement in Section 5 to remove the indication that the Clearing Agencies have discretion to not maintain policies and procedures governing the development and maintenance of R&W Plans.

12. Proposed Change To Correct Error Regarding Reporting Line of DTCC Internal Audit Department

The Clearing Agencies are proposing a change to the Framework to correct an error in Section 3.1.3, which currently states Internal Audit has a direct reporting line to the Risk Committees of the Boards. This statement is incorrect, as Internal Audit has a direct reporting line to the Audit Committees of the Boards. The Clearing Agencies would correct this error by making a minor revision to Section 3.1.3 of the Framework. In addition, the Clearing Agencies are proposing to change references of ''Audit Committee'' to ''Audit Committees'' to reflect that each of the Boards has an audit committee.

2. Statutory Basis

The Clearing Agencies believe that the proposed changes are consistent with Section 17A(b)(3)(F) of the Act[30] and Rules 17Ad–22(e)(22) and (e)(23) promulgated under the Act,[31] for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.[32] The proposed changes would (1) add a description of how the Clearing Agencies address compliance with Rule 17Ad–22(e)(22), (2) update the descriptions of certain matters in the Risk Management Framework, and (3) clarify and correct other statements within the Framework, as described above. By addressing the Clearing Agencies' compliance with Rule 17Ad–22(e)(22), creating clearer, updated descriptions and correcting errors, the Clearing Agencies believe that the proposed changes would make the Risk Management Framework more effective in providing an overview of the important risk management activities of the Clearing Agencies, as described therein.

As described in the Initial Filing, the risk management functions described in the Risk Management Framework allow the Clearing Agencies to continue to promote the prompt and accurate clearance and settlement of securities transactions, and continue to assure the safeguarding of securities and funds which are in their custody or control or for which they are responsible notwithstanding the default of a member of an affiliated family. The proposed changes to describe policies that address to the Clearing Agencies' communication standards and improve the clarity and accuracy of the descriptions of risk management functions within the Framework would assist the Clearing Agencies in carrying out these risk management functions. Therefore, the Clearing Agencies believe these proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[33]

Rule 17Ad–22(e)(22) under the Act requires that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to use, or at a minimum accommodate, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing, and settlement.[34] The Framework would describe a policy maintained by the Clearing Agencies that (1) identifies the communication standards and data forms used by the Clearing Agencies for payment, clearing and settlement that are regarded as accepted industry standards for transactions processed through the Clearing Agencies, and (2)

[29] CPMI and the Board of IOSCO, Public quantitative disclosure standards for central counterparties (February 26, 2015), *available at https://www.iosco.org/library/pubdocs/pdf/IOSCOPD475.pdf.*

[30] 15 U.S.C. 78q–1(b)(3)(F).

[31] 17 CFR 240.17Ad–22(e)(22) and (e)(23).

[32] 15 U.S.C. 78q–1(b)(3)(F).

[33] *Id.*

[34] 17 CFR 240.17Ad–22(e)(22).

provides that the Clearing Agencies would accommodate relevant internationally accepted communication procedures and standards when new industry standards are introduced. By describing the Clearing Agencies' use of accepted industry communication standards and their policy of supporting new industry standards when introduced, this policy, and a supporting communication standards document, both support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22).[35] Therefore, the Clearing Agencies believe that the proposed rule change to include this policy in the Risk Management Framework is consistent with Rule 17Ad–22(e)(22).[36]

Rule 17Ad–22(e)(23) under the Act requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for publicly disclosing relevant basic data on transaction volume and values, and a comprehensive public disclosure that describes their material rules, policies, and procedures regarding their legal, governance, risk management, and operating framework, accurate in all material respects at the time of publication.[37] Section 4.1 of the Framework currently describes how the Clearing Agencies provide their respective participants with information and incentives to enable them, and, through them, their customers, to understand, monitor, manage and contain the risks they pose to the respective Clearing Agencies, and identifies some of the tools the Clearing Agencies provide to their participants to facilitate this understanding. The proposed rule change would revise Section 4.1 of the Framework to state that those tools and activities support the Clearing Agencies' compliance with Rule 17Ad–22(e)(23) under the Act.[38] By describing these actions, including the publication of disclosure frameworks and quantitative disclosures, the Clearing Agencies believe that the proposed change to the Risk Management Framework is consistent with Rule 17Ad–22(e)(23).[39]

(B) Clearing Agency's Statement on Burden on Competition

The Clearing Agencies do not believe that the proposed changes to the Framework described above would have any impact, or impose any burden, on competition. As described above, the proposed rule changes would improve the comprehensiveness of the Framework by including a description of the Clearing Agencies' compliance with Rule 17Ad–22(e)(22) under the Act and would also improve the clarity and accuracy of the descriptions of certain matters within the Framework. Therefore, the proposed changes are technical and non-material in nature, relating mostly to the operation of the Framework rather than the risk management functions described therein. As such, the Clearing Agencies do not believe that the proposed rule changes would have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[40] and Rule 19b–4(f)(6) thereunder.[41]

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–FICC–2020–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–FICC–2020–007. 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 FICC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–FICC–2020–007 and should be submitted on or before August 5, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15207 Filed 7–14–20; 8:45 am]

BILLING CODE 8011–01–P

[35] *Id.*

[36] *Id.*

[37] 17 CFR 240.17Ad–22(e)(23).

[38] *Id.*

[39] *Id.*

[40] 15 U.S.C. 78s(b)(3)(A).

[41] 17 CFR 240.19b–4(f)(6).

[42] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89267; File No. SR–CboeBZX–2020–042]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Accommodate Exchange Listing and Trading of Options-Linked Securities

July 9, 2020.

On May 15, 2020, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend BZX Rule 14.11(d) (Securities Linked to the Performance of Indexes and Commodities (Including Currencies)) to permit Exchange listing and trading of Options-Linked Securities. The proposed rule change was published for comment in the **Federal Register** on June 3, 2020.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission will either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is July 18, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates September 1, 2020 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–CboeBZX–2020–042).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15204 Filed 7–14–20; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 88968 (May 28, 2020), 85 FR 34270.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89271; File No. SR–NSCC–2020–012]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Clearing Agency Risk Management Framework

July 9, 2020.

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 July 7, 2020, National Securities Clearing Corporation (''NSCC'') 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 clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] 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 proposed rule change consists of amendments to the Clearing Agency Risk Management Framework (''Risk Management Framework'' or ''Framework'') of NSCC and its affiliates, The Depository Trust Company (''DTC'') and Fixed Income Clearing Corporation (''FICC,'' and together with NSCC and DTC, the ''Clearing Agencies''). Specifically, the proposed rule change would (1) include a description of a set of policies that addresses the Clearing Agencies' compliance with Rule 17Ad–22(e)(22) of the Standards for Covered Clearing Agencies (''Standards''), under the Act,[5] (2) update the Risk Management Framework to reflect recent changes to certain processes and other matters described in the Framework, and changes to the status of documents identified in the Framework; and (3) clarify the descriptions of certain matters within the Framework to improve comprehensiveness and correct errors, as further described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency 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

1. Purpose

The Clearing Agencies adopted the Risk Management Framework [6] to provide an outline for how each of the Clearing Agencies (i) maintains a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities; (ii) comprehensively manages legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by it; (iii) identifies, monitors, and manages risks related to links it establishes with one or more clearing agencies, financial market utilities, or trading markets; and (iv) meets the requirements of its participants and the markets it serves efficiently and effectively. In this way, the Risk Management Framework currently supports the Clearing Agencies' compliance with Rules 17Ad–22(e)(1), (3), (20) and (21) of the Standards,[7] as described in the Initial Filing. In addition to setting forth the manner in which each of the Clearing Agencies addresses these requirements, the Risk Management Framework also contains a section titled ''Framework Ownership and Change Management'' that, among other matters, describes the Framework ownership and the required governance process for review and approval of changes to the Framework.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] 17 CFR 240.17Ad–22(e)(22).

[6] *See* Securities Exchange Act Release No. 81635 (September 15, 2017), 82 FR 44224 (September 21, 2017) (SR–DTC–2017–013; SR–NSCC–2017–012; SR–FICC–2017–016) (''Initial Filing'').

[7] 17 CFR 240.17Ad–22(e)(1), (3), (20) and (21).

In connection with the annual review and approval of the Framework by the Board of Directors of each of NSCC, DTC and FICC (each a ''Board'' and collectively, the ''Boards''), the Clearing Agencies are proposing to make certain revisions to the Framework.

The proposed changes would add a new Section 4.4 to describe a policy and a communication standard document that support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22), which requires the Clearing Agencies to establish, implement, maintain and enforce written policies and procedures reasonably designed to use, or at a minimum accommodate, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing, and settlement.[8]

The proposed changes would also update the Risk Management Framework to reflect (1) a change to the name of the Vendor Risk Management group to the Third Party Risk Management group; (2) a change to the format of the Balanced Business Scorecard, which is an internal performance management tool used to measure the effectiveness of various aspects of the operations of The Depository Trust & Clearing Corporation (''DTCC'') and its subsidiaries, including the Clearing Agencies; and (3) the filing of certain documents identified in the Framework, pursuant to Section 19(b)(1) of the Act,[9] and the rules thereunder, and Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled the Payment, Clearing, and Settlement Supervision Act of 2010,[10] and the rules thereunder (collectively, ''Filing Requirements''), as described in greater detail below.

The proposed changes would also clarify and enhance the descriptions in the Risk Management Framework to (1) identify the requirement of Rule 17Ad–22(e)(3)(i) under the Act that the Framework be reviewed and approved by the Boards on an annual basis; [11] (2) identify the role of the DTCC Legal Department in supporting the management of legal risks that arise in or are borne by the Clearing Agencies; (3) enhance the description of the DTCC Risk Department as ''Second Line of Defense,'' (4) enhance the description of the DTCC Internal Audit Department as ''Third Line of Defense;'' (5) enhance the description of a policy relating to the establishment and governance of internal management committees; (6) enhance the description of the processes designed to maintain comprehensive policies, procedures and other documents; (7) clarify that certain activities described in the Framework that relate to the public disclosure of material information, including market data, address the Clearing Agencies' compliance with Rule 17Ad–22(e)(23) under the Act; [12] (8) enhance the description of the management of systemic risks by describing the role of the Systemic Risk Council; (9) correct a sentence by removing an unnecessary phrase; and (10) enhance the descriptions of certain actions by removing the indication that the Clearing Agencies have discretion in engaging in those actions.

Finally, the proposed changes would correct an error in the Risk Management Framework to identify the Audit Committees of the Boards as the committees to which the DTCC Internal Audit Department has a direct reporting line. Each of these proposed changes is described below.

i. Proposed Amendments To Describe Policies That Address Compliance With Rule 17Ad–22(e)(22)

First, the proposed changes would add a new Section 4.4 to the Framework to describe a policy maintained by the Clearing Agencies to use and accommodate relevant internationally accepted communication procedures and standards to facilitate efficient payment, clearing, and settlement, to support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22).[13]

The policy describes how the communication standards and data formats that are currently used by the Clearing Agencies for payment, clearing, and settlement are regarded as accepted industry standards for transactions processed through the Clearing Agencies. The policy also provides that the Clearing Agencies would accommodate new industry standards that are considered internationally accepted communication procedures and standards. The new Section 4.4 would also state that the Clearing Agencies maintain a communication standard document that supports this policy.

The Clearing Agencies are proposing to amend the Risk Management Framework to adopt a new Section 4.4 that would describe these documents, which support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22).[14]

ii. Proposed Amendments To Update the Framework

Second, the proposed changes would update the Risk Management Framework to reflect recent developments with respect to certain processes and other matters described in the Framework, and changes to the status of documents described in the Framework, as described below.

1. Proposed Change To Identify Third Party Risk Management

Section 4 of the Risk Management Framework outlines ways in which each of the Clearing Agencies manages certain risks that arise in or are borne by it. Specifically, Section 4.2 describes the management of risks related to material interdependencies and external links that may be established by the Clearing Agencies. The Clearing Agencies represent that management of risks presented by vendors and other material service providers is guided by a function within the Operational Risk Management group within the Group Chief Risk Office . This function was previously referred to as ''Vendor Risk Management.'' While the role and responsibilities of this risk management function have not changed, its name has recently been changed to ''Third Party Risk Management'' to clarify that the function covers any material third party service provider that provides a service to a DTCC entity.

The Clearing Agencies are proposing to amend Section 4.2.1 of the Risk Management Framework to reflect this name change and to clarify that the function covers any material third party service provider that provides a service to a DTCC entity by adding ''Third Party'' as a new defined term. The Clearing Agencies are also proposing to identify the existing policy and procedure that is maintained to manage these risks.

2. Proposed Change to Description of Balanced Business Scorecard

Section 4.3 of the Risk Management Framework addresses certain processes implemented by the Clearing Agencies in order to be efficient and effective in meeting the requirements of their respective participants and the markets they serve.[15] One of the methods the Clearing Agencies use to meet these requirements is the periodic creation of a Balanced Business Scorecard, which provides insight into the effectiveness of the Clearing Agencies' operations,

[8] 17 CFR 240.17Ad–22(e)(22).

[9] 15 U.S.C. 78s(b)(1).

[10] 12 U.S.C. 5465(e)(1).

[11] 17 CFR 240.17Ad–22(e)(3)(i).

[12] 17 CFR 240.17Ad–22(e)(23).

[13] 17 CFR 240.17Ad–22(e)(22).

[14] *Id.*

[15] Such processes support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(21) under the Act. 17 CFR 240.17Ad–22(e)(21).

information technology service levels, financial performance, human capital, and their respective participants' experience.

Previously, a Balanced Business Scorecard (referred to as the ''Core Balance Business Scorecard'') was created for the Clearing Agencies, and a separate Balanced Business Scorecard was created for the other subsidiaries of DTCC. Recently, these two tools merged, and only one Balanced Business Scorecard (now referred to as the ''DTCC Balanced Business Scorecard'') is created, which addresses DTCC and each of its subsidiaries, including each of the Clearing Agencies. While the new, enterprise-wide Balanced Business Scorecard reports its conclusions on a less granular, enterprise-wide basis, it is created using the same set of metrics as the legacy Clearing Agencies version. Therefore, the Balanced Business Scorecard continues to support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(21) under the Act.[16] The Balanced Business Scorecard now reports those metrics in the context of the DTCC enterprise, at a less granular level.

The Clearing Agencies are proposing to amend Section 4.3 of the Risk Management Framework to reflect the change in format of the Balanced Business Scorecard described above.

3. Proposed Change to Description of Certain Documents To Reflect Filing Pursuant To Filing Requirements

Following the adoption of the Risk Management Framework, certain documents that are identified in the Framework were filed pursuant to the Filing Requirements. The Clearing Agencies are proposing to revise the descriptions of these documents to reflect this change.

Section 3.3 of the Framework describes certain frameworks that are maintained by the Clearing Agencies and provide an outline for certain policies and procedures that address, in whole or in part, the management of operational, liquidity, credit, market, collateral, and other risks. This section identified five such frameworks, the Clearing Agency Operational Risk Management Framework, the Clearing Agency Liquidity Risk Management Framework, the Clearing Agency Securities Valuation Framework, the Clearing Agency Stress Testing Framework, and the Clearing Agency Model Risk Management Framework. Each of these frameworks has been filed pursuant to the applicable Filing Requirements and adopted by the Clearing Agencies.[17] The Clearing Agencies are proposing to update Section 3.3 to reflect this change.

Section 5 of the Risk Management Framework describes the plans that are maintained by each of the Clearing Agencies for their recovery or orderly wind-down (''R&W Plans''). The R&W Plans were still in development when the Framework was adopted, but have since been finalized, approved by the Boards, filed pursuant to the Filing Requirements, and adopted by the Clearing Agencies.[18] Therefore, the Clearing Agencies are proposing to update Section 5 to reflect these developments, and to describe the ongoing governance of the R&W Plans.

iii. Proposed Amendments To Clarify, Enhance, and Correct Descriptions in the Framework

Finally, the proposed changes would enhance the descriptions of certain matters within the Risk Management Framework to improve its clarity and comprehensiveness and correct an error, as described below.

1. Proposed Change To Correct Annual Approval of Framework by Boards

Section 2 of the Risk Management Framework addresses the Framework's ownership and change management. This section currently states that the Framework should be reviewed by the document owner no less frequently than annually but does not specifically identify the requirement that the Framework also be approved by the Boards on an annual basis. The Clearing Agencies are proposing to correct the Framework to include the requirement that the Framework be approved by the Boards, or a duly authorized committee of the Boards, annually.

Rule 17Ad–22(e)(3) under the Act requires that the Clearing Agencies maintain a sound risk management framework for comprehensively managing the risks that arise in or are borne by the Clearing Agencies, including investment and custody risks.[19] Rule 17Ad–22(e)(3)(i) under the Act requires that the risk management policies, procedures, and systems that are maintained in compliance with Rule 17Ad–22(e)(3) be subject to review on a specified periodic basis and be approved by the Boards annually.[20] As stated above, the Framework provides an outline for how each of the Clearing Agencies comprehensively manages legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by it, as required by Rule 17Ad–22(e)(3) under the Act.[21] Therefore, the Risk Management Framework is reviewed and approved by the Boards annually, as required by Rule 17Ad–22(e)(3)(i) under the Act.[22]

The Clearing Agencies are proposing to amend Section 2 of the Framework to state that the Framework shall be approved by the Boards, or a duly authorized committee of the Boards, annually. The proposed change would correct the Framework to include this requirement, which is aligned with the applicable requirements of Rule 17Ad–22(e)(3)(i) under the Act.[23]

2. Proposed Change To Identify DTCC Legal Department's Role in Management of Clearing Agencies' Legal Risks

Section 3.1 of the Risk Management Framework describes the ''three lines of defense'' approach adopted by each of the Clearing Agencies for identifying, assessing, measuring, monitoring, mitigating, and reporting the risks that arise in or are borne by it. Currently, this section outlines the role of each line of defense, and specifically describes the roles of the DTCC Risk Department (''Risk Department'') and DTCC Internal Audit Department (''Internal Audit'') within this risk management approach. The DTCC Legal Department (''Legal Department'') also plays a particular role in the three lines of defense approach by supporting each line of defense in the management of legal risks.

While the Legal Department is currently identified as part of the

[16] *Id.*

[17] *See* Securities Exchange Act Release Nos. 81745 (September 28, 2017), 82 FR 46332 (October 4, 2017) (SR–DTC–2017–014; SR–NSCC–2017–013; SR–FICC–2017–017) (Operational Risk Management Framework); 82377 (December 21, 2017), 82 FR 61617 (December 28, 2017) (SR–DTC–2017–004; SR–NSCC–2017–005; SR–FICC–2017–008) (Liquidity Risk Management Framework); 82006 (November 2, 2017), 82 FR 51892 (November 8, 2017) (SR–DTC–2017–016; SR–NSCC–2017–016; SR–FICC–2017–020) (Securities Valuation Framework); 82368 (December 19, 2017), 82 FR 61082 (December 26, 2017) (SR–DTC–2017–005; SR–FICC–2017–009; SR–NSCC–2017–006) (Stress Testing Framework); and 81485 (August 25, 2017), 82 FR 41433 (August 31, 2017) (SR–DTC–2017–008; SR–FICC–2017–014; SR–NSCC–2017–008) (Model Risk Management Framework).

[18] *See* Securities Exchange Act Release Nos. 83972 (August 28, 2018), 83 FR 44964 (September 4, 2018) (SR–DTC–2017–021); 83953 (August 27, 2018), 83 FR 44381 (August 30, 2018) (SR–DTC–2017–803); 83974 (August 28, 2018), 83 FR 44988 (September 4, 2018) (SR–NSCC–2017–017); 83955 (August 27, 2018), 83 FR 44340 (August 30, 2018) (SR–NSCC–2017–805); 83973 (August 28, 2018), 83 FR 44942 (September 4, 2018) (SR–FICC–2017–021); 83954 (August 27, 2018), 83 FR 44361 (August 30, 2018) (SR–FICC–2017–805).

[19] 17 CFR 240.17Ad–22(e)(3).

[20] 17 CFR 240.17Ad–22(e)(3)(i).

[21] 17 CFR 240.17Ad–22(e)(3).

[22] 17 CFR 240.17Ad–22(e)(3)(i).

[23] *Id.*

control functions that form the second line of defense in Section 3.1.2, its particular role is not separately described. Therefore, the Clearing Agencies are proposing to update the introduction of Section 3.1 to state that the Legal Department supports each line of defense in the management of legal risks. This proposed change would more clearly describe the particular role of the Legal Department in this risk management approach.

3. Proposed Change To Enhance Description of DTCC's Risk Department as ''Second Line of Defense'' in Risk Management

As stated above, Section 3.1 of the Risk Management Framework describes the ''three lines of defense'' approach to risk management adopted by the Clearing Agencies. Section 3.1.2 describes the particular role of the Risk Department as the second line of defense within this risk management approach. The Clearing Agencies are proposing to amend this Section 3.1.2 to enhance the description of the Risk Department's role, including by providing details relating to the role of the Operational Risk Management group within the Risk Department. The proposed amendments would describe how the Operational Risk Management group addresses and escalates incidents based on a risk rating of those incidents. In addition, the proposed change would clarify the description relating to the procedures, processes, tools, mechanisms, analyses, and testing controls employed by the Risk Department and indicate that such procedures, etc. are subject to the parameters set forth in Section 3.3, which discusses the Filing Requirements and document standards relating to policies, procedures, frameworks and certain related documents. In addition, the Clearing Agencies are proposing to add a defined term in Section 3.1 to reflect that the Risk Department refers to the Risk Department of DTCC. The proposed changes would more clearly describe the particular role of the Risk Department in this risk management approach.

4. Proposed Change To Enhance Description of DTCC's Internal Audit Department as ''Third Line of Defense'' in Risk Management

Section 3.1.3 of the Risk Management Framework describes the particular role of Internal Audit as the third line of defense within the risk management approach. The Clearing Agencies are proposing to amend this Section 3.1.3 to enhance the description of Internal Audit's role, including by providing a clearer description of the responsibilities of Internal Audit, making grammatical changes to certain descriptions to improve readability, and removing references to Internal Audit as providing an advisory role to the Clearing Agencies. By removing references to advisory services, the proposed changes would conform the Risk Management Framework to the charter of the Audit Committees of the Boards, where similar changes have been made to reinforce the group's role as the third line of defense in risk management and its independence and objectivity in the performance of assurance services. In addition, the Clearing Agencies are proposing to add a defined term in Section 3.1 to clarify that Internal Audit refers to the Internal Audit Department of DTCC.

5. Proposed Change To Enhance Description of Policy Regarding Management Committees and Oversight

Section 3.2 of the Risk Management Framework states that a set of senior management committees provides oversight of various aspects of the Clearing Agencies' activities, including risk management, and describes the policy that sets forth the requirements for establishing and governing these committees. The Clearing Agencies are proposing to amend Section 3.2 by including a reference to the described document and providing a clearer and more complete description of the contents of this policy and the ongoing governance requirements of senior management committees. The proposed changes would not make any substantive changes to this description.

6. Proposed Change To Enhance Description of Management of Policies, Procedures, and Other Documents

Section 3.3.1 of the Risk Management Framework states that the Clearing Agencies maintain comprehensive policies and procedures designed to identify, measure, monitor and manage the risks that arise in or are borne by the Clearing Agencies, and describes a set of standards the Clearing Agencies have established for creating and managing these documents. The Clearing Agencies are proposing to amend the description of these standards. The proposed amendments to Section 3.3.1 would re-word the descriptions of these standards by, for example, more clearly describing the governance of these documents, how these standards provide guidance on reviews of these documents by document owners, and the role of the document owners in adhering to these standards. The proposed changes would not make any substantive changes to this description.

7. Proposed Change To Clarify Regulatory Basis of Certain Public Disclosures

Section 4.1 of the Risk Management Framework states that the Clearing Agencies provide their respective participants with information and incentives to enable them, and, through them, their customers, to understand, monitor, manage, and contain the risks they pose to the respective Clearing Agencies, and identifies some of the tools the Clearing Agencies provide to their participants to facilitate this understanding. The Clearing Agencies are proposing to amend Section 4.1 to make clarifying edits.

First, the proposed amendments would clarify that the tools and activities described in Section 4.1 support the Clearing Agencies' compliance with Rule 17Ad–22(e)(23) under the Act.[24] Rule 17Ad–22(e)(23) requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for publicly disclosing relevant basic data on transaction volume and values, and a comprehensive public disclosure that describes their material rules, policies, and procedures regarding their legal, governance, risk management, and operating framework, accurate in all material respects at the time of publication.[25] Certain matters described in Section 4.1 of the Framework, including the publication of disclosure frameworks and quantitative disclosures (described below), support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(23).[26] Therefore, the Clearing Agencies would update the introduction to Section 4.1, and make a conforming change to Section 1 of the Framework, to refer to Rule 17Ad–22(e)(23).[27]

Second, the proposed amendments would correct a statement in Section 4.1 of the Framework regarding the disclosure frameworks posted to the DTCC website for each of the Clearing Agencies on a biennial basis, which provide a comprehensive description of how the businesses and operations of the Clearing Agencies reflect the Principles for financial market infrastructures, issued by the Committee on Payment and Settlement Systems (''CPSS'') and the Technical Committee of the International Organization of

[24] 17 CFR 240.17Ad–22(e)(23).

[25] *Id.*

[26] *Id.*

[27] *Id.*

Securities Commissions (''IOSCO'').[28] These disclosure frameworks also address how the businesses and operations of the Clearing Agencies reflect the Standards. Therefore, the Clearing Agencies would correct this statement in Section 4.1 regarding the scope of the disclosure frameworks by also referring to the Standards.

Finally, the proposed amendments would correct a statement in Section 4.1 of the Framework regarding the quantitative disclosures that are posted to the DTCC website on a quarterly basis, which disclose certain quantitative data and other information as set out in the Public quantitative disclosure standards for central counterparties published by CPMI and IOSCO.[29] Currently, Section 4.1 states that these disclosures relate to the Clearing Agencies. However, these disclosures are only required for central counterparties and, as such, only relate to NSCC and FICC, and not DTC. The Clearing Agencies would correct this error by replacing ''Clearing Agencies'' with ''NSCC and FICC, as central counterparties'' in Section 4.1 of the Framework.

8. Proposed Change To Enhance Description of Governance of Systemic Risk Management

The proposed change would enhance the description of the governance of systemic risk management in Section 4.2.1 by including a description of the Systemic Risk Council, the frequency of this Council's meetings, and stating that matters discussed at these meetings may be escalated to the Management Risk Committee or the Board Risk Committee when appropriate. The proposed changes would improve the descriptions in the Framework by providing additional details regarding the governance of systemic risk management.

9. Proposed Change To Enhance Description of Management of Risk Related to Other External Links

The proposed change would enhance the description of the management of risks related to external links in Section 4.2.2 by identifying a policy and a procedure that are maintained by the Clearing Agencies to govern this process. The proposed change would improve the disclosures in the Framework by providing a clear reference to these documents.

10. Proposed Change To Remove Unnecessary Phrase

The proposed change would remove an unnecessary phrase '', is set forth in'' that is incorrectly at the end of a sentence in Section 1 of the Framework.

11. Proposed Change To Rephrase Sentences That Incorrectly Indicate Discretion in Taking Certain Actions

The proposed change would rephrase four sentences in the Framework that currently indicate the action described is discretionary. First, the proposed change would rephrase a statement in Section 4.2.1 to remove the indication that the Clearing Agencies have discretion to not manage risks related to participants and settlement banks. Second, the proposed change would rephrase a statement in Section 4.2.1 to remove the indication that the Clearing Agencies have discretion to not maintain policies, procedures or templates relating to the management of third-party risks. Third, the proposed change would rephrase a statement in Section 4.2.2 to remove the indication that the General Counsel's Office has discretion in reviewing certain key link arrangements. Finally, the proposed change would rephrase a statement in Section 5 to remove the indication that the Clearing Agencies have discretion to not maintain policies and procedures governing the development and maintenance of R&W Plans.

12. Proposed Change To Correct Error Regarding Reporting Line of DTCC Internal Audit Department

The Clearing Agencies are proposing a change to the Framework to correct an error in Section 3.1.3, which currently states Internal Audit has a direct reporting line to the Risk Committees of the Boards. This statement is incorrect, as Internal Audit has a direct reporting line to the Audit Committees of the Boards. The Clearing Agencies would correct this error by making a minor revision to Section 3.1.3 of the Framework. In addition, the Clearing Agencies are proposing to change references of ''Audit Committee'' to ''Audit Committees'' to reflect that each of the Boards has an audit committee.

2. Statutory Basis

The Clearing Agencies believe that the proposed changes are consistent with Section 17A(b)(3)(F) of the Act[30] and Rules 17Ad–22(e)(22) and (e)(23) promulgated under the Act,[31] for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.[32] The proposed changes would (1) add a description of how the Clearing Agencies address compliance with Rule 17Ad–22(e)(22), (2) update the descriptions of certain matters in the Risk Management Framework, and (3) clarify and correct other statements within the Framework, as described above. By addressing the Clearing Agencies' compliance with Rule 17Ad–22(e)(22), creating clearer, updated descriptions and correcting errors, the Clearing Agencies believe that the proposed changes would make the Risk Management Framework more effective in providing an overview of the important risk management activities of the Clearing Agencies, as described therein.

As described in the Initial Filing, the risk management functions described in the Risk Management Framework allow the Clearing Agencies to continue to promote the prompt and accurate clearance and settlement of securities transactions, and continue to assure the safeguarding of securities and funds which are in their custody or control or for which they are responsible notwithstanding the default of a member of an affiliated family. The proposed changes to describe policies that address to the Clearing Agencies' communication standards and improve the clarity and accuracy of the descriptions of risk management functions within the Framework would assist the Clearing Agencies in carrying out these risk management functions. Therefore, the Clearing Agencies believe these proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[33]

Rule 17Ad–22(e)(22) under the Act requires that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to use, or at a minimum accommodate, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing,

[28] CPSS and the Technical Committee of IOSCO, Principles for financial market infrastructures (April 16, 2012), *available at http://www.bis.org/cpmi/publ/d101a.pdf.* In 2014, CPSS became the Committee on Payments and Market Infrastructures (''CPMI'').

[29] CPMI and the Board of IOSCO, Public quantitative disclosure standards for central counterparties (February 26, 2015), *available at https://www.iosco.org/library/pubdocs/pdf/IOSCOPD475.pdf.*

[30] 15 U.S.C. 78q–1(b)(3)(F).

[31] 17 CFR 240.17Ad–22(e)(22) and (e)(23).

[32] 15 U.S.C. 78q–1(b)(3)(F).

[33] *Id.*

and settlement.[34] The Framework would describe a policy maintained by the Clearing Agencies that (1) identifies the communication standards and data forms used by the Clearing Agencies for payment, clearing and settlement that are regarded as accepted industry standards for transactions processed through the Clearing Agencies, and (2) provides that the Clearing Agencies would accommodate relevant internationally accepted communication procedures and standards when new industry standards are introduced. By describing the Clearing Agencies' use of accepted industry communication standards and their policy of supporting new industry standards when introduced, this policy, and a supporting communication standards document, both support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22).[35] Therefore, the Clearing Agencies believe that the proposed rule change to include this policy in the Risk Management Framework is consistent with Rule 17Ad–22(e)(22).[36]

Rule 17Ad–22(e)(23) under the Act requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for publicly disclosing relevant basic data on transaction volume and values, and a comprehensive public disclosure that describes their material rules, policies, and procedures regarding their legal, governance, risk management, and operating framework, accurate in all material respects at the time of publication.[37] Section 4.1 of the Framework currently describes how the Clearing Agencies provide their respective participants with information and incentives to enable them, and, through them, their customers, to understand, monitor, manage and contain the risks they pose to the respective Clearing Agencies, and identifies some of the tools the Clearing Agencies provide to their participants to facilitate this understanding. The proposed rule change would revise Section 4.1 of the Framework to state that those tools and activities support the Clearing Agencies' compliance with Rule 17Ad–22(e)(23) under the Act.[38] By describing these actions, including the publication of disclosure frameworks and quantitative disclosures, the Clearing Agencies believe that the proposed change to the Risk Management Framework is consistent with Rule 17Ad–22(e)(23).[39]

(B) Clearing Agency's Statement on Burden on Competition

The Clearing Agencies do not believe that the proposed changes to the Framework described above would have any impact, or impose any burden, on competition. As described above, the proposed rule changes would improve the comprehensiveness of the Framework by including a description of the Clearing Agencies' compliance with Rule 17Ad–22(e)(22) under the Act and would also improve the clarity and accuracy of the descriptions of certain matters within the Framework. Therefore, the proposed changes are technical and non-material in nature, relating mostly to the operation of the Framework rather than the risk management functions described therein. As such, the Clearing Agencies do not believe that the proposed rule changes would have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[40] and Rule 19b–4(f)(6) thereunder.[41]

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–NSCC–2020–012 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–2020–012. 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 NSCC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–NSCC–2020–012 and should be submitted on or before August 5, 2020.

[34] 17 CFR 240.17Ad–22(e)(22).

[35] *Id.*

[36] *Id.*

[37] 17 CFR 240.17Ad–22(e)(23).

[38] *Id.*

[39] *Id.*

[40] 15 U.S.C. 78s(b)(3)(A).

[41] 17 CFR 240.19b–4(f)(6).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15208 Filed 7–14–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89281; File No. SR–CBOE–2020–061]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend Its Fees Schedule With Respect To Expiring Fee Waivers and Incentive Programs

July 9, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2020, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''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 the Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its Fees Schedule with respect to expiring fee waivers and incentive programs. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule to (1) make permanent the MSCI EAFE Index (''MXEA'') options and MSCI Emerging Markets Index (''MXEF'') options Lead Market Maker (''LMM'') Incentive Program that is otherwise set to expire June 30, 2020, (2) amend the Global Trading Hours (''GTH'') Cboe Volatility Index (''VIX'') options and VIX Weekly (''VIXW'') options LMM Incentive Program, (3) amend the S&P 500 Index (SPX) options and SPX Weekly (''SPXW'') options LMM Incentive Program and (4) clarify that certain facility fees will be waived while the trading floor is operating in a modified manner. The Exchange proposes to implement these amendments to its Fees Schedule on July 1, 2020.

MXEA and MXEF LMM Incentive Program

The Exchange proposes to permanently adopt the financial program for LMMs appointed in MXEA and MXEF options.[3] Currently, if the appointed LMM in MXEA and MXEF provides continuous electronic quotes during Regular Trading Hours that meet or exceed the above heightened quoting standards in at least 90% of the MXEA and MXEF series 80% of the time in a given month, the LMM will receive a payment for that month in the amount of $20,000 per class, per month. The Fees Schedule currently provides that this program will be in place through June 30, 2020. The Exchange believes that making this incentive program permanent would continue to encourage LMM(s) in MXEA and MXEF to serve in an important role as LMMs that provide significant liquidity in these options, which, in turn, provides, and would continue to provide, greater trading opportunities, added market transparency and enhanced price discovery for all market participants in MXEA and MXEF. The Exchange notes, too, that it also proposes to remove obsolete language regarding applicability of the program in February 2019.

GTH VIX/VIXW LMM Program

The Exchange currently offers a financial incentive program for LMMs quoting in GTH appointed in VIX/VIXW.[4] Currently, pursuant to the Fees Schedule, if an LMM in VIX/VIXW provides continuous electronic quotes during GTH that meet or exceed the below heightened quoting standards in at least 99% of each of the VIX and VIXW series, 90% of the time in a given month, the LMM will receive a rebate for that month in the amount of $20,000 for VIX and $5,000 for VIXW.

Premium level	Maximum allowable width
$0.00–$100.00	$10.00
$100.01–$200.00	16.00
Greater than $200.00	24.00

Additionally, a GTH LMM in VIX/VIXW is not currently obligated to satisfy the heightened quoting standards described in the table above. Rather, an LMM is eligible to receive the rebate if it satisfies the heightened quoting standards above, which the Exchange believes encourages LMMs to provide liquidity during GTH. The Exchange may also consider other exceptions to this quoting standard based on demonstrated legal or regulatory requirements or other mitigating circumstances.

The Exchange now proposes to amend the GTH VIX/VIXW LMM Incentive Program to apply new heightened quoting standards to VIX during GTH.[5] Specifically, a GTH LMM in VIX must provide continuous electronic quotes during GTH that meet or exceed the new proposed heightened quoting standards (below), in the same percentage of the series (*i.e.,* 99%) for the same percentage of the time (*i.e.,* 90%) in a given month in order to receive a rebate for that month in the proposed amount of $15,000.

[42] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Cboe Options Fees Schedule, ''MSCI LMM Incentive Program'' Table; *and* Securities Exchange Act Release Nos. 83585 (July 2, 2018), 83 FR 31825 (July 9, 2018) (SR–CBOE–2018–050); 85114 (February 12, 2019), 84 FR 4878 (February 19, 2019) (SR–CBOE–2019–006); 86361 (July 11, 2019), 84 FR 34243 (July 17, 2019) (SR–CBOE–2019–031); and 87953 (January 13, 2020), 85 FR 3091 (January 17, 2020) (SR–CBOE–2020–001).

[4] The Exchange notes that an LMM appointed in VIX also holds an appointment in VIXW.

[5] The current heighted quoting standard is not changing for VIXW.

Premium level	Expiring		Near term		Mid term		Long term	
	15 days or less		15 days to 60 days		61 days to 270 days		271 days or greater	
	Width	Size	Width	Size	Width	Size	Width	Size
$0.00–$1.00	$0.75	25	$0.50	50	$0.50	50	$1.00	10
$1.01–$3.00	1.00	15	0.75	25	0.75	25	1.00	10
$3.01–$5.00	1.00	15	0.75	25	0.75	25	1.20	7
$5.01–$10.00	1.50	10	1.00	10	1.00	10	2.00	5
$10.01–$30.00	2.50	5	1.50	5	2.50	5	4.00	3
Greater than $30.00	5.00	3	3.00	5	5.00	3	7.00	2

Additionally, each LMM that meets the proposed heightened quoting standards for VIX options will receive a proposed rebate in the amount of $0.03 per contract applied to all VIX/VIXW options contracts executed in its Market-Maker capacity during Regular Trading Hours. The Exchange also proposes to remove obsolete language regarding applicability of the program in February 2020.

Meeting or exceeding the heightened quoting standards in VIX, as proposed, to receive the proposed compensation payment remains optional for a GTH LMM. The Exchange notes that the heightened quoting standard currently in place will continue to apply to VIXW, as will the $5,000 rebate offered for meeting such standards in VIXW.

Additionally, the Exchange notes that a GTH VIX/VIXW LMM may need to undertake expenses to be able to quote at a significantly heightened standard in VIX/VIXW, such as purchase more logical connectivity based on its increased capacity needs. The Exchange believes the proposed heightened quoting requirements and rebate for VIX under the GTH VIX/VIXW LMM Incentive Program is designed to continue to encourage GTH LMMs to provide significant liquidity in VIX options during GTH. The Exchange also notes that the proposed heightened quoting standards are substantially similar to the detail and format (specific expiration categories and corresponding premiums, quote widths, and sizes) of the heightened quoting standards currently in place for GTH SPX/SPXW LMMs.[6]

GTH SPX/SPXW LMM Program

As indicated above, the Exchange also currently offers a financial incentive program for LMMs quoting in GTH appointed in SPX/SPXW.[7] Currently, pursuant to the Fees Schedule, if an LMM in SPX/SPXW provides continuous electronic quotes during GTH that meet or exceed the below heightened quoting standards in at least 99% of each of the SPX and SPXW series, 90% of the time in a given month, the LMM will receive a rebate for that month in the amount of $10,000 for SPX and $10,000 for SPXW.

Premium level	Expiring		Near term		Mid term		Long term	
	7 days or less		8 days to 60 days		61 days to 270 days		271 days or greater	
	Width	Size	Width	Size	Width	Size	Width	Size
$0.00–$5.00	$0.50	10	$0.40	25	$0.60	15	$1.00	10
$5.01–$15.00	2.00	7	1.60	18	2.40	11	4.00	7
$15.01–$50.00	5.00	5	4.00	13	6.00	8	10.00	5
$50.01–$100.00	10.00	3	8.00	8	12.00	5	20.00	3
$100.01–$200.00	20.00	2	16.00	5	24.00	3	40.00	2
Greater than $200.00	30.00	1	24.00	3	36.00	1	60.00	1

Like with the GTH LMM VIX/VIXW Incentive Program, a GTH LMM in SPX/SPXW is not currently obligated to satisfy the heightened quoting standards described in the table above, but instead is eligible to receive the rebate if they satisfy the heightened quoting standards above, which are also designed to encourage LMMs to provide liquidity during GTH. The Exchange may also consider other exceptions to this quoting standard based on demonstrated legal or regulatory requirements or other mitigating circumstances.

The Exchange proposes to decrease the percentage of each the SPX and SPXW series that an LMM must quote in order to receive the current rebate under the GTH SPX/SPXW incentive program from at least 99% of the series to at least 85% of the series. The proposed decrease is intended to ease the heightened quoting standard for GTH LMMs in the appointed class so that LMMs are further incentivized to provide significant liquidity in GTH in SPX/SPXW to meet the incrementally less difficult heighten quoting standards.

Exchange Operating in Modified State—Footnote 24 Clarification

The Exchange recently submitted a rule filing, SR–CBOE–2020–058, that adopted footnote 24 of the Fees Schedule to govern pricing changes that apply for the duration of time the Exchange trading floor is being operated in a modified manner in connection with the COVID–19 pandemic.[8] Footnote 24 provides, among other things, for certain pricing changes and waives certain facilities fees for the duration of time the Exchange is operating in a modified state in connection with the COVID–19 pandemic. The Exchange now proposes to amend footnote 24 to clarify that, when the Exchange trading floor is being operate in a modified manner in connection with the COVID–19 pandemic, TPHs will not be assessed fees on facility services that are not currently in use, which may be due to the TPH being unable to be present on the trading floor as a consequence of the pandemic. Specifically, the proposed

[6] *See* Fees Schedule, ''GTH SPX/SPXW Incentive Program'' Table.

[7] The Exchange notes that an LMM appointed in SPX also holds an appointment in SPXW.

[8] *See* SR–CBOE–2020–058 (filed June 24, 2020).

amendment provides that, if a TPH is unable to utilize designated facility services while the trading floor is operating in a modified state, corresponding fees, including for Exchangefone maintenance, single line maintenance, intra floor lines, voice circuits, data circuits at local carrier (entrance), and data circuits at in-house frame, will not be assessed. The proposed change also incorporates references to footnote 24 next to each of the above-listed designated facility services within the Facility Fees (per month) Table in the Fees Schedule.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[11] which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

MXEA and MXEF LLM Incentive Program

The Exchange believes it is reasonable to make the MXEA and MXEF LMM Incentive Program permanent because the Exchange wants to continue incentivizing the LMM(s) in these products to continue to provide liquid and active markets in these products to encourage its growth. The Exchange notes that without the proposed financial incentive, there may not be sufficient incentive for TPHs to undertake an obligation to quote at heightened levels, which could result in lower levels of liquidity to the detriment of all market participants. The Exchange believes that the program is equitable and not unfairly discriminatory to only offer this financial incentive to MXEA and MXEF LMM(s), because it benefits all market participants trading in these options to encourage the LMM(s) to satisfy the heightened quoting standard, in turn, increasing liquidity and providing more trading opportunities, tighter spreads, added market transparency, and enhanced price discovery. Indeed, the Exchange notes that LMMs provide a crucial role in providing quotes and the opportunity for market participants to trade products, including MXEA and MXEF, which can lead to increased volume, thereby providing for a robust market. In addition, the Exchange notes that all Market-Maker types (*i.e.* LMMs, DPMs, as well as Primary Market-Makers (''PMMs'')) take on a number of obligations, including quoting obligations, that other market participants do not have. Such Market-Makers have added market-making and regulatory requirements, which normally do not apply to other market participants. For example, Market-Makers have obligations to maintain continuous markets, engage in a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and to not make bids or offers or enter into transactions that are inconsistent with a course of dealing. Also, if a MSCI LMM does not satisfy the heightened quoting standard, then it simply will not receive the offered per class payment for that month.

GTH VIX/VIXW LMM and GTH SPX/SPXW Incentive Programs

The Exchange believes the amended heightened quoting standards and rebate amount, along with the proposed credit during RTH for meeting the heightened quoting standards, in VIX series are reasonably designed to continue to incentivize an appointed LMM to meet the GTH quoting standards for VIX, thereby providing liquid and active markets, which facilitates tighter spreads, increased trading opportunities, and overall enhanced market quality to the benefit of all market participants. The Exchange believes that the proposed changes to the program in connection with the heightened quoting standards in VIX are reasonable in that they are substantially similar to the detail and format (specific expiration categories and corresponding premiums, quote widths, and sizes) of the heightened quoting standards currently in place for GTH SPX/SPXW LMMs.[12] Quote widths and sizes typical in VIX options differ from that in SPX options, therefore, the proposed heightened quoting requirements reflect quote widths and sizes that align with the market characteristic in VIX options. Additionally, the Exchange believes the 15 days or less expiration for the ''near term'' expiration category (as opposed to a 7 days or less expiration for the near term) makes it easier for GTH LMMs in VIX to satisfy the near-term heightened quoting standard category, as proposed, because higher volatility generally occurs within the 7 days or less expiration timeframe, wherein it becomes more difficult for LMMs to quote within specified widths and sizes. Moreover, the Exchange believes that reducing the monthly rebate from $20,000 to $15,000, and adopting a credit for all VIX/VIXW executions in a Market-Maker capacity, for meeting the heightened quoting standards in VIX, as proposed, is reasonable and equitable as it will continue to offer a monthly rebate, though reduced, that falls within a comparable realm of rebates offered for other, similar LMM incentive programs [13] while also offering an additional opportunity in which a GTH VIX LMM may receive an additional rebate on its activity in VIX/VIXW.

Similarly, the Exchange believes it is reasonable to ease the percentage of the SPX/SPXW series for which a GTH SPX/SPXW LMM must quote in order to receive the existing rebate pursuant to the GTH SPX/SPXW LMM Incentive Program, because the proposed change is reasonably designed to slightly decrease the difficulty in meeting the heightened quoting standards, which, in turn, provides increased incentivize for GTH LMMs to provide significant liquidity in SPX/SPXW during GTH. The Exchange believes that although the proposed change decreases the amount of the series that a GTH LMM may quote in order to receive the program's rebate, the proposed percentage (85%) remains well above even half the series, and, the Exchange notes, the 90% timing requirement will remain in place; consequently, a GTH LMM must continue to submit significant liquidity in order to receive the rebate.

The Exchange believes it is equitable and not unfairly discriminatory to continue to only offer this financial incentive to GTH VIX/VIXW and GTH

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(4).

[12] *See supra* note 5.

[13] *See* Fees Schedule, ''MSCI LMM Incentive Program'' Table, which offers appointed LMMs payment of $20,000 for meeting certain heightened quoting requirements; *and* ''GTH SPX/SPXW Incentive Program'' Table, which offers appointed LMMs payment of $10,000 for meeting certain heightened quoting requirements.

SPX/SPXW LMMs, as amended, because it benefits all market participants trading VIX/VIXW and SPX/SPXW during GTH to encourage the LMMs to satisfy the heightened quoting standard, which ensures, and may even provide increased, liquidity, which thereby may provide more trading opportunities and tighter spreads. Indeed, the Exchange notes that the GTH LMMs serve a crucial role in providing quotes and the opportunity for market participants to trade VIX/VIXW and SPX/SPXW, which can lead to increased volume, providing for robust markets. The Exchange ultimately wishes to sufficiently incentive a GTH LMM to provide liquid and active markets in VIX/VIXW and SPX/SPXW during GTH to encourage liquidity. The Exchange believes that the programs, even as amended, will continue to encourage increased quoting to add liquidity in VIX, and in SPX/SPXW, thereby protecting investors and the public interest. The Exchange also notes that a GTH LMM may have added costs each month that it needs to undertake in order to satisfy that heightened quoting standard (*e.g.,* having to purchase additional logical connectivity). The Exchange believes the proposed amendments are equitable and not unfairly discriminatory because they equally apply to any TPH that is appointed as a GTH VIX/VIXW or SPX/SPXW LMM, respectively. Additionally, if a GTH LMM does not satisfy the heightened quoting standard in VIX/VIXW or SPX/SPXW, as applicable, for any given month, then it simply will not receive the offered payment for that month.

Exchange Operating in Modified State—Footnote 24 Clarification

The Exchange believes the proposed rule change to waive fees for designated facility services unable to be utilized when the trading floor is operated in a modified manner is reasonable because TPHs will not be assessed fees for such facility services that they are not currently using as a result of not accessing the trading floor due to the COVID–19 pandemic. The Exchange notes that footnote 24 already provides for waivers of certain facilities fees while the Exchange trading floor is operating in a modified manner and such facilities are not being used by TPHs. The proposed change merely clarifies that the fees normally assessed for designated facility services (Exchangefone maintenance, single line maintenance, intra floor lines, voice circuits, data circuits at local carrier (entrance), and data circuits at in-house frame) will be included in the list of floor-related fees for facility services that are waived when the services are not in use due to COVID–19 complications. The Exchange believes that it is reasonable not to charge a service fee to TPHs when such services are not being utilized as a result of the Exchange operating in a modified manner. The listed facility fees each apply to a service that a TPH may not be utilizing because such TPH is not currently active on the trading floor and using the facilities as a result of the COVID–19 pandemic. The Exchange believes the proposed rule change relating to waiving certain service fees is also reasonable, equitable and not unfairly discriminatory as it applies equally to all floor TPHs who do not use such services while the trading floor is operating in a modified manner.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on intramarket or intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes the proposed rule change does impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed changes to existing incentive programs that already apply to all LMMs appointed to the applicable classes (*i.e.* MXEF, MXEA, VIX, VIXW, SPX, SPXW) in a uniform manner. To the extent these LMMs receive a benefit that other market participants do not, as stated, LMMs have different obligations and are held to different standards. For example, LMMs play a crucial role in providing active and liquid markets in their appointed products, thereby providing a robust market which benefits all market participants. Such Market-Makers also have obligations and regulatory requirements that other participants do not have. The Exchange also notes that the incentive programs are designed to attract additional order flow to the Exchange, wherein greater liquidity benefits all market participants by providing more trading opportunities, tighter spreads, and added market transparency and price discovery, and signals to other market participants to direct their order flow to those markets, thereby contributing to robust levels of liquidity.

The Exchange notes the proposed changes in connection with footnote 24 are not intended to address any competitive issue, but rather to address fee changes it believes are reasonable because the trading floor is currently operating in a modified manner in connection with COVID–19 in order to help protect the safety and welfare of individuals access the trading floor. The Exchange does not believe that the proposed rule change to waive the service fees for those services not currently in use will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed changes apply equally to all floor TPHs not utilizing such facility services.

The Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes in connection with the incentive programs only affect trading on Cboe Options, as the incentive programs apply to transactions in products exclusively listed on Cboe Options. The Exchange notes it operates in a highly competitive market. In addition to Cboe Options, TPHs have numerous alternative venues that they may participate on and director their order flow, including 15 other options exchanges, as well as off-exchange venues, where competitive products are available for trading. Based on publicly available information, no single options exchange has more than 18% of the market share of executed volume of options trades.[14] Therefore, no exchange possesses significant pricing power in the execution of option order flow. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [15] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission*, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing

[14] *See* Cboe Global Markets, U.S. Options Market Volume Summary by Month (June 29, 2020), available at *http://markets.cboe.com/us/options/market_share/.*

[15] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .'' [16] Accordingly, the Exchange does not believe its proposed changes to the incentive programs impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe that the proposed rule change in connection with the waiver of certain designated facility service fees will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed changes only affect trading on the Exchange in limited circumstances.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [17] and paragraph (f) of Rule 19b–4 [18] 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. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2020–061 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2020–061. 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2020–061, and should be submitted on or before August 5, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

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[16] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89272; File No. SR–CboeEDGX–2020–034]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change To Add the Consolidated Audit Trail Industry Member Compliance Rules to the List of Minor Rule Violations in Rules 8.15 and 25.3

July 9, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 8, 2020, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') proposes to add the Consolidated Audit Trail (''CAT'') industry member compliance rules (''CAT Compliance Rules'') to the list of minor rule violations in Rules 8.15 and 25.3. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In order to implement the National Market System Plan Governing the Consolidated Audit Trail (the ''CAT NMS Plan'' or ''Plan'') the Exchange codified the CAT Compliance Rules in Rules 4.5 through 4.16.[3] The CAT NMS Plan was filed by the Plan Participants to comply with Rule 613 of Regulation NMS under the Exchange Act,[4] and each Plan Participant accordingly has adopted the same compliance rules as the Exchange's Rules 4.5 through 4.16. The common compliance rules adopted by each Plan Participant are designed to require industry members to comply with the provisions of the CAT NMS Plan, which broadly calls for industry members to record and report timely and accurate customer, order, and trade information relating to activity in NMS Securities and OTC Equity Securities.

Rule 8.15 provides for disposition of certain violations through assessment of fines in lieu of conducting a formal disciplinary proceeding. Rule 8.15.01, specifically, sets forth the list of specific EDGX Equities Rules under which a any Member, associated person of a Member, or registered or non-registered employee of a Member may be subject to a fine for violations of such Rules. Rule 25.3 provides the same for EDGX Options Rule violations, under which an Options Member, associated person of an Options Member, or registered or non-registered employee of an Options Member may be subject to a fine for violations of such Rules. The Exchange proposes to amend Rule 8.15.01 and Rule 25.3 to add the CAT Compliance Rules in Rules 4.5 through 4.16 to the list of rules in Rule 8.15.01 and Rule 25.3 eligible for disposition pursuant to a minor fine; specifically, under proposed Rule 8.15.01(i) and proposed Rule 25.3(g).[5] Proposed Rule 8.15.01(i) and proposed Rule 25.3(g) each provide that for failures to comply with the Consolidated Audit Trail Compliance Rule requirements of Rules 4.5 through 4.16, the Exchange may impose a minor rule violation fine of up to $2,500. The Exchange may seek other disciplinary action more serious violations.

The Exchange is coordinating with the Financial Industry Regulatory Authority, Inc. (''FINRA'') and other Plan Participants to promote harmonized and consistent enforcement of all the Plan Participants' CAT Compliance Rules. The Commission recently approved a Rule 17d–2 Plan under which the regulation of CAT Compliance Rules will be allocated among Plan Participants to reduce regulatory duplication for industry members that are members of more than one Participant (''common members'').[6] Under the Rule 17d–2 Plan, the regulation of CAT Compliance Rules with respect to common members that are members of FINRA is allocated to FINRA. Similarly, under the Rule 17d–2 Plan, responsibility for common members of multiple other Plan Participants and not a member of FINRA will be allocated among those other Plan Participants, including to the Exchange. For those non-common members who are allocated to EDGX pursuant to the Rule 17d–2 Plan, the Exchange and FINRA have entered into a Regulatory Services Agreement (''RSA'') pursuant to which FINRA will assist the Exchange with conducting surveillance, investigation, examination, and enforcement activity in connection with the CAT Compliance Rules on the Exchange's behalf. The Exchange expects that the other exchanges will be entering into similar RSAs.

The Exchange notes that this proposal is based upon the FINRA filing to amend FINRA Rule 9217 in order to add FINRA's corresponding CAT Compliance Rules to FINRA's list of rules that are eligible for minor rule violation plan treatment.[7] The Exchange also notes that the New York Stock Exchange LLC (''NYSE'') submitted a filing to amend its Minor Rule Violation Plan (''MRVP'') to add its CAT Compliance Rules in a manner consistent with FINRA's proposal,[8] and other Plan Participants intend to submit the same. Thus, in order to achieve consistency with FINRA and the other Plan Participants, the Exchange proposes to adopt fines up to $2,500 in connection with minor rule fines for violations of the CAT Compliance Rules (Rules 4.5 through 4.16) in proposed Rules 8.15.01(i) and 25.3(g) under the Exchange's MRVP. In connection with FINRA's proposed amendment to FINRA Rule 9217 to make FINRA's CAT Compliance Rules MRVP eligible, FINRA has stated that it will apply the minor fines for CAT Compliance Rules in the same manner that FINRA has for its similar existing audit trail-related rules.[9] Accordingly, in order to promote regulatory consistency, the Exchange plans to do the same. Specifically, application of a minor fine with respect to CAT Compliance Rule violations will be guided by the same factors that FINRA references in its filing. However, more formal disciplinary proceedings may be warranted instead of minor rule dispositions in certain circumstances such as where violations prevent regulatory users of the CAT from performing their regulatory functions. Where minor rule dispositions are appropriate, the following factors help guide the determination of fine amounts:

- Total number of reports that are not submitted or submitted late;
- The timeframe over which the violations occur;
- Whether violations are batched;
- Whether the violations are the result of the actions of one individual or the result of faulty systems or procedures;
- Whether the firm has taken remedial measures to correct the violations;
- Prior minor rule violations within the past 24 months;
- Collateral effects that the failure has on customers; and
- Collateral effects that the failure has on the Exchange's ability to perform its regulatory function.[10]

Upon effectiveness of this rule change, the Exchange will publish a regulatory bulletin notifying its Members and/or Options Members of the rule change and the specific factors that will be considered in connection with assessing minor rule fines described above.

[3] *See* Securities Exchange Act Release No. 79949 (February 2, 2017), 82 FR 9765 (February 8, 2017) (SR–BatsEDGX–2017–08); *and* 80256 (March 15, 2017), 82 FR 14526 (March 21, 2017) (Order Approving Proposed Rule Changes To Adopt Consolidated Audit Trail Compliance Rules).

[4] 17 CFR 242.613.

[5] FINRA's maximum fine for minor rule violations under FINRA Rule 9216(b) is $2,500. The Exchange will apply an identical maximum fine amount for eligible violations of Rules 4.5 through 4.16 to achieve consistency with FINRA and also amend its minor rule violation plan (''MRVP'') to include such fines. Like FINRA, the Exchange would be able to pursue a fine greater than $2,500 for violations of Rules 4.5 through 4.16 in a regular disciplinary proceeding or a letter of consent under Chapter 8 as appropriate. Any fine imposed in excess of $2,500 or not otherwise covered by Rule 19d–1(c)(2) of the Act would be subject to prompt notice to the Commission pursuant to Rule 19d–1 under the Act. As noted below, in assessing the appropriateness of a minor rule fine with respect to CAT Compliance Rules, the Exchange will be guided by the same factors that FINRA utilizes. *See* text accompanying notes 7–8 [sic], *infra*.

[6] *See* Securities Exchange Act Release No. 88366 (March 12, 2020), 85 FR 15238 (March 17, 2020).

[7] *See* Securities Exchange Act Release No. 88870 (May 14, 2020), 85 FR 30768 (May 20, 2020) (SR–FINRA–2020–013).

[8] *See* SR–NYSE–2020–51 (filed June 12, 2020).

[9] *See supra* note 7; *see* also FINRA Notice to Members 04–19 (March 2004) available at *https://www.finra.org/rules-guidance/notices/04-19* (providing specific factors used to inform dispositions for violations of OATS reporting rules).

[10] *See id*.

For the foregoing reasons, the Exchange believes that the proposed rule change will result in a coordinated, harmonized approach to CAT Compliance Rule enforcement across Plan Participants that will be consistent with the approach FINRA has taken with the CAT rules.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Minor rule fines provide a meaningful sanction for minor or technical violations of rules when the conduct at issue does not warrant stronger, immediately reportable disciplinary sanctions. The inclusion of a rule in the Exchange's MRVP does not minimize the importance of compliance with the rule, nor does it preclude the Exchange from choosing to pursue violations of eligible rules through a letter of consent if the nature of the violations or prior disciplinary history warrants more significant sanctions. Rather, the Exchange believes that the proposed rule change will strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities in cases where full disciplinary proceedings are unwarranted in view of the minor nature of the particular violation. The Exchange believes the option to impose a minor rule sanction gives the Exchange additional flexibility to administer its enforcement program in the most effective and efficient manner while still fully meeting the Exchange's remedial objectives in addressing violative conduct.[14] Specifically, the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because it will provide the Exchange the ability to issue a minor rule fine for violations of the CAT Compliance Rules in Rules 4.5 through 4.16 where a more formal disciplinary action may not be warranted or appropriate consistent with the approach of other Plan Participants for the same conduct.

In connection with the fine level specified in the proposed rule change, adding proposed Rules 8.15.01(i) and 25.3(g) to specifically provide that for violations of the CAT Compliance Rules in Rules 4.5 through 4.16 the Exchange may impose a fine not to exceed $2,500 would further the goal of transparency within the Exchange's rules. Adopting the same cap as FINRA for minor rule fines in connection with the CAT Compliance Rules would also promote regulatory consistency across self-regulatory organizations.

The Exchange further believes that the proposed amendments to Rule 8.15.01 and Rule 25.3 are consistent with Section 6(b)(6) of the Act,[15] which provides that members and persons associated with members shall be appropriately disciplined for violation of the provisions of the rules of the exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction. As noted, the proposed rule change would provide the Exchange (both EDGX Equities and EDGX Options) the ability to sanction minor or technical violations of Rules 4.5 through 4.16 pursuant to the Exchange's rules.

Finally, the Exchange also believes that the proposed change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[16] Rule 8.15 does not preclude a Member, associated person of a Member, or registered or non-registered employee of a Member, and Rule 25.3 does not preclude an Options Member, associated person of an Options Member, or registered or non-registered employee of an Options Member, from contesting an alleged violation and receiving a hearing on the matter with the same procedural rights through a litigated disciplinary proceeding.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with making the CAT Compliance Rules in Rules 4.5 through 4.16 eligible for a minor rule fine disposition, thereby strengthening the Exchange's ability to carry out its oversight and enforcement functions and deter potential violative conduct. Also, as stated above, the proposed rule change is consistent with similar proposals recently filed by FINRA and NYSE, and other Plan Participants intend to submit the same.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. 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–CboeEDGX–2020–034 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.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] Pursuant to Rule 8.15(a) and (e) and Rule 25.3, the Exchange has the discretion to impose a fine in lieu of commencing a disciplinary proceeding for a violation that is minor in nature. Rule 8.15(e) states specifically that nothing in Rule 8.15 requires the Exchange to impose a fine pursuant to Rule 8.15 with respect to the violation of any Rule included in any such listing. Rule 25.3 states specifically that the Exchange is not required to proceed under said Rules as to any rule violation and may, whenever such action is deemed appropriate, commence a disciplinary proceeding under Chapter VIII (Discipline) rules as to any such violation.

[15] 15 U.S.C. 78f(b)(6).

[16] 15 U.S.C. 78f(b)(7) and 78f(d).

All submissions should refer to File Number SR–CboeEDGX–2020–034. 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–CboeEDGX–2020–034 and should be submitted on or before August 5, 2020.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[17] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[18] which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act[19] which require that the rules of an exchange enforce compliance with, and provide appropriate discipline for, violations of Commission and Exchange rules. Finally, the Commission finds that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, as required by Rule 19d–1(c)(2) under the Act,[20] which governs minor rule violation plans.

As stated above, the Exchange proposes to add the CAT Compliance Rules to the list of minor rule violations in Rules 8.15 and 25.3 to be consistent with the approach FINRA has taken for minor violations of its corresponding CAT Compliance Rules.[21] The Commission has already approved FINRA's treatment of CAT Compliance Rules violations when it approved the addition of CAT Compliance Rules to FINRA's MRVP.[22] As noted in that order, and similarly herein, the Commission believes that Exchange's treatment of CAT Compliance Rules violations as part of its MRVP provides a reasonable means of addressing violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. However, the Commission expects that, as with FINRA, the Exchange will continue to conduct surveillance with due diligence and make determinations based on its findings, on a case-by-case basis, regarding whether a sanction under the rule is appropriate, or whether a violation requires formal disciplinary action. Accordingly, the Commission believes the proposal raises no novel or significant issues.

For the same reasons discussed above, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[23] for approving the proposed rule change prior to the thirtieth day after the date of publication of the notice of the filing thereof in the **Federal Register**. The proposal merely adds the CAT Compliance Rules to the Exchange's MRVP and harmonizes its application with FINRA's application of CAT Compliance Rules under its own MRVP. Accordingly, the Commission believes that a full notice-and-comment period is not necessary before approving the proposal.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act[24] and Rule 19d–1(c)(2) thereunder,[25] that the proposed rule change (SR–CboeEDGX–2020–034) be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15209 Filed 7–14–20; 8:45 am]

BILLING CODE 8011–01–P

[17] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78f(b)(1) and 78f(b)(6).

[20] 17 CFR 240.19d–1(c)(2).

[21] As discussed above, the Exchange has entered into a Rule 17d–2 Plan and an RSA with FINRA with respect to the CAT Compliance Rules. The Commission notes that, unless relieved by the Commission of its responsibility, as may be the case under the Rule 17d–2 Plan, the Exchange continues to bear the responsibility for self-regulatory conduct and liability for self-regulatory failures, not the self-regulatory organization retained to perform regulatory functions on the Exchange's behalf pursuant to an RSA. *See* Securities Exchange Release No. 61419 (January 26, 2010), 75 FR 5157 (February 1, 2010) (SR–BATS–2009–031), note 93 and accompanying text.

[22] *See supra* note 7.

[23] 15 U.S.C. 78s(b)(2).

[24] 15 U.S.C. 78s(b)(2).

[25] 17 CFR 240.19d–1(c)(2).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89282; File No. SR–CboeEDGX–2020–033]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend Its Fees Schedule

July 9, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2020, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''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 the Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX Options'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule for its options platform (EDGX Options), specifically, certain Customer Volume Tiers and Market Maker Volume Tiers, effective July 1, 2020.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 options venues to which market participants may direct their order flow. Based on publicly available information, no single options exchange has more than 18% of the market share and currently the Exchange represents only approximately 4% of the market share.[3] Thus, in such a low-concentrated and highly competitive market, no single options exchange, including the Exchange, possesses significant pricing power in the execution of option order flow. 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 to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange's Fees Schedule sets forth standard rebates and rates applied per contract. For example, the Exchange provides standard rebates ranging from $0.01 up to $0.21 per contract for Customer orders in both Penny and Non-Penny Securities and assesses fees ranging from $0.01 up to $0.75 per contract for Market Maker, Away Market Maker, Broker Dealer, Firm, Joint Back Office, and Professional orders in both Penny and Non-Penny Securities. The Exchange also offers tiered pricing which provides Members [4] opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Footnote 1 of the Fee Schedule currently offers four Customer Volume Tiers which provide enhanced rebates between $0.10 and $0.21 per contract for qualifying Customer orders which meet certain liquidity thresholds and yield fee code PC [5] or NC.[6] Footnote 2 of the Fee Schedule currently offers eight Market Maker Volume Tiers which provide reduced fees between $0.17 and $0.03 per contract for qualifying Market Maker orders which meet certain liquidity thresholds and yield fee code PM [7] or NM.[8] Under the current Customer Volume and Market Maker Volume Tiers, a Member may receive an enhanced rebate where the Member meets certain thresholds of ADV [9] that are greater than or equal to a percentage of average OCV [10] for respective qualifying orders. The Exchange now proposes to amend Customer Volume Tiers 1 through 4 and Market Maker Volume Tiers 7 and 8.

The Exchange proposes to amend Customer Volume Tier 1 and 2 to specify that a Member must reach an ADV in Customer orders that are Non-Crossing orders (that is, orders not executed in a two sided auction mechanism such as the Automated Improvement Mechanism (''AIM'') or the Solicitation Auction Mechanism (''SAM'') or in a crossing mechanism such as a Qualified Contingent Cross (''QCC'')). Currently, both Tier 1 and Tier 2 provide that Members may achieve the respective tiers if they achieve an ADV in Customer orders as a certain percentage that is greater than or equal to average OCV. The Exchange proposes to specify that, for these two tiers, Members receive the enhanced rebates currently in place if they achieve an ADV in Customer Non-Crossing orders as a certain percentage that is greater than or equal to average OCV. The Exchange notes that the ADV thresholds of average OCV will remain the same for these tiers. The Exchange is proposing to specify that Customer Non-Crossing orders may be submitted in order to achieve Customer Volume Tier 1 and Tier 2 as the Fee Schedule already provides for opportunities for which Customer Crossing orders, specifically, may achieve enhanced rebates comparable to the enhanced rebates offered under Tiers 1 and 2.[11] In this way, the Exchange believes the proposed change will incentivize Members to submit more Non-Crossing orders into the EDGX Options Book (as opposed to submitting more Customer orders into the Exchange's crossing auctions/mechanisms to achieve the tiers' criteria, which, as stated, already receive comparable enhanced rebates and reduced fees under the Fee Schedule) in order to achieve Customer Volume Tiers 1 and 2.

The Exchanges next proposes to amend Customer Volume Tiers 3 and 4 by increasing, in each, a percentage of ADV into average OCV within existing criteria and adding to each tier a new, additional criteria that a Member must meet to receive the existing enhanced rebate. The Exchange notes that the proposed changes do not alter the current enhanced rebates provided under Customer Volume Tier 3 and 4. Specifically, Tier 3 currently provides an enhanced rebate of $0.21 for Members that have an ADV in Customer

[3] *See* Cboe Global Markets U.S. Options Market Monthly Volume Summary (June 25, 2020), available at *https://markets.cboe.com/us/options/market_statistics/*.

[4] *See* Exchange Rule 1.5(n).

[5] Fee code PC is appended to Customer, Penny orders and receive a standard rebate of $0.01.

[6] Fee code NC is appended to Customer Non-Penny orders and receive a standard rebate of $0.01.

[7] Fee code PM is appended to liquidity adding Market Maker, Penny orders and are assessed a standard fee of $0.20.

[8] Fee code NM is appended to liquidity adding Market Maker, Non-Penny orders and are assessed a standard fee of $0.20.

[9] ''ADV'' means average daily volume calculated as the number of contracts added or removed, combined, per day. ADV is calculated on a monthly basis, excluding contracts added or removed on any day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during regular trading hours (''Exchange System Disruption'') and on any day with a scheduled early market close.

[10] ''OCV'' is Options Clearing Corporation (''OCC'') Customer Volume which is the total equity and ETF options volume that clears in the Customer range at the OCC for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption and on any day with a scheduled early market close.

[11] *See* Fee Schedule, Footnote 6, AIM and SAM Pricing, which provides an enhanced rebate of $0.11 (or does not assess a fee) for qualifying Customer orders executed via the Exchange's crossing auctions.; *see also* Footnote 7, QCC Initiator/Solicitation Rebate Tiers, which provide enhanced rebates between $0.05 and $0.11 for QCC Agency Orders or Solicitation Agency Orders.

orders greater than or equal to 0.75% of average OCV. Tier 4 currently also provides enhanced rebate of $0.21 for Members that have (1) an ADV in Customer orders greater than or equal 0.60% of average OCV and (2) an ADV in Customer or Market Maker orders greater than or equal to 1.00% of average OCV. The Exchange proposes to first increase the ADV in Customer orders from greater than or equal to 0.75% to 1.00% threshold of average OCV in Tier 3 and from greater than or equal to 0.60% to 0.75% threshold of average OCV in prong 1 in Tier 4. The Exchange also proposes to add an additional prong of criteria in each Tier 3 and Tier 4. As proposed, a Member may receive the existing enhanced rebate under Tier 3 if the Member meets the current criteria and, also, has an ADV in Customer Non-Crossing orders of greater than or equal to 0.40% of average OCV. Likewise, a Member may receive the existing enhanced rebate under Tier 4 if the Member meets the current (two) criteria and, as proposed, has an ADV in Customer Non-Crossing orders of greater than or equal to 0.40% of average OCV. The proposed increases in Customer order ADV as a percentage of average OCV in Tier 3 and Tier 4 are intended to incrementally increase the level of difficulty in achieving each of these tiers, thus, incentivizing Members to increase their overall Customer order flow to the Exchange by encouraging those Members to strive for the different, incrementally more difficult tier criteria under the proposed tiers to receive the enhanced rebates. The proposed additional prongs of criteria per each tier are also designed to incrementally increase the level of difficulty in achieving Tier 3 and Tier 4, while, like the proposed changes to Tier 1 and Tier 2 described above, specifically incentivizing Members to submit Non-Crossing Customer orders to the Exchange's Order Book.

Likewise, the Exchange also proposes to amend Market Maker Volume Tiers 7 and 8 by increasing, in each, certain percentages of ADV into average OCV within existing criteria. Currently, Tier 7 provides a reduced fee of $0.04 for Members that have (1) an ADV in Customer orders greater than or equal to 0.30% of average OCV, (2) an ADV in Customer or Market Maker orders greater than or equal to 0.50% of average OCV, (3) an ADV in AIM Agency Orders greater than or equal to 0.15% of average OCV, and (4) an ADV in complex Customer orders (yielding fee codes ZA, ZB, ZC, or ZD) [12] greater than or equal to 5,000 contracts. Currently, Tier 8 provides a reduced fee of $0.03 for Members that have (1) an ADV in Customer orders greater than or equal to 0.70% of average OCV, (2) an ADV in Customer or Market Maker orders greater than or equal to 1.10% of average OCV, (3) an ADV in AIM Agency Orders greater than or equal to 0.15% of average OCV, and (4) an ADV in complex Customer orders (yielding fee codes ZA, ZB, ZC, or ZD) greater than or equal to 0.20% of average OCV. Regarding Tier 7, the Exchange proposes to increase the percentage of ADV in Customer orders from 0.30% to 0.70%,of average OCV in prong 1, to increase the percentage of ADV in AIM Agency Orders from 0.15% to 0.30% of average OCV in prong 3, and to update prong 4 from ADV in complex Customer orders as greater than or equal to 5,000 to greater than or equal to 0.10% of average OCV. Regarding Tier 8, the Exchange proposes to increase the percentage of ADV in Customer orders from 0.70% to 1.00% in prong 1, and to increase the percentage of ADV in AIM Agency Orders from 0.15% to 0.75% in prong 3. Like the proposed changes to Customer Volume Tiers 3 and 4, the Exchange notes that the proposed changes to criteria in Market Maker Volume Tiers 7 and 8 incrementally increase the level of difficulty in achieving these tiers, thus, are designed to incentivize Members to increase their Customer and/or AIM Agency order flow to the Exchange by encouraging those Members to strive for the different, incrementally more difficult tier criteria under the proposed tiers to receive the reduced rates.

The Exchange believes that almost all of the proposed fee changes are designed to incentivize more Customer order flow and, particularly, a majority of the proposed changes are intended to direct an increase of Customer order flow to the EDGX Options Order Book. An increase in Customer order flow will create more trading opportunities, which, in turn attracts Market-Makers. A resulting increase in Market-Maker activity may facilitate tighter spreads, which may lead to an additional increase of order flow from other market participants, further contributing to a deeper, more liquid market to the benefit of all market participants by creating a more robust and well-balanced market ecosystem. Additionally, the proposed change in connection with the AIM Agency order ADV threshold in Market Maker Volume Tier 8 is intended to incentivize an increase in AIM Agency orders submitted to an AIM auction in order to achieve the proposed tier. The Exchange believes increased AIM Agency order flow results in price improvement opportunities for customers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[13] in general, and furthers the objectives of Section 6(b)(4),[14] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5) [15] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule change reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members.

In particular, the Exchange believes the proposed tiers are reasonable because they amend existing opportunities in a manner that incentivizes increased Customer or AIM Agency order flow via incrementally more challenging criteria in order to receive the same enhanced rebates or reduced fees on a Member's qualifying

[12] Fee code ZA is appended to Complex Customer (contra Non-Customer), Penny orders and receives a standard rebate of $0.45; fee code ZB is appended to Complex Customer (contra Non-Customer), Non-Penny orders and received a standard rebate of $0.80; fee code ZC is appended to Complex Customer (contra Customer) orders and is assessed no charge; and fee code ZD is appended to Complex Customer order that legs into Simple Book and is assessed no charge.

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78f.(b)(5).

orders. The Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges,[16] including the Exchange,[17] and are reasonable, equitable and non-discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Additionally, as noted above, the Exchange operates in a highly competitive market. The Exchange is only one of several options venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. Competing options exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds and offer comparable pricing to members for achieving such tiers.[18]

The Exchange believes the proposed modification to specify that Non-Crossing Customer order may be submitted in achieving the existing criteria in Customer Volume Tiers 1 and 2, as well as the proposed additional criteria in Customer Volume Tiers 3 and 4 for which a Member must submit Non-Crossing Customer order ADV as a percentage of average OCV, in order to receive the current enhanced rebates under Customer Volume Tiers 1 through 4 is reasonable because it is designed to direct Customer order flow to the Exchange's Order Book, as opposed to into the Exchange's crossing auctions/mechanisms to achieve the tiers' criteria, which already receive comparable enhanced rebates and reduced fees under the Fee Schedule.[19] An increase in Customer order flow to the Order Book results in an increase of transaction opportunities within the Order Book, attracting Market Maker quotes which, in turn, facilitates tighter spreads on the Exchange and signals additional corresponding increase in order flow from other market participants. Increased overall order flow benefits all investors by deepening the Exchange's liquidity pool, potentially providing even greater execution incentives and opportunities, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection. Similarly, the proposed increases in overall Customer order and AIM Agency order ADV as a percentage of OCV (as proposed within Customer Volume Tiers 3 and 4 and Market Maker Volume Tiers 7 and 8) are reasonable modifications to the existing criteria because they are designed to incrementally increase the difficulty in achieving these tiers, thereby incentivizing Members to increase their overall Customer order flow and/or AIM Agency order flow, which benefits customers by resulting in increased price improvement opportunities within the auctions, to receive the exiting enhanced rebates and/or reduced fees.

Further, the Exchange believes that the proposed rule changes are reasonable as they do not represent a significant departure from the current criteria offered in the Fee Schedule and represent proportional increases in difficulty per adjacent tiers. For example, the Exchange proposes to simultaneously increase the Customer order ADV thresholds of average OCV in Customer Volume Tier 3 and Tier 4 and provide the same additional criteria in each. As a result, the Exchange believes the level of difficulty in achieving Tier 3 and Tier 4 will remain approximately the same. Likewise, the Exchange proposes to simultaneously increase the ADV thresholds in the corresponding prongs between Tier 7 and Tier 8. That is, prong 1 under both Tier 7 and Tier 8, criteria of which consists of Customer order ADV as a percentage of average OCV, and prong 3 under both Tier 7 and Tier 8, criteria of which consists of AIM Agency order ADV as a percentage of average OCV, will experience incremental increases of ADV as a percentage of average OCV. Thus, the step up in difficulty from Tier 7 to Tier 8 will remain approximately the same. Additionally, the Exchange notes that the proposed change in prong 4 under Tier 7 to amend the threshold of 5,000 contracts to 0.10% of average OCV is better aligned with, and is a proportional step down from, the 0.20% of average OCV in corresponding prong 4 under Tier 8. The Exchange again notes that the proposed rule changes do not alter the amount of any of the current rebates or fees in place.

The Exchange believes that the proposal represents an equitable allocation of rebates and is not unfairly discriminatory because all Members will continue to be eligible for Customer Volume Tiers 1 through 4 and Market Maker Volume Tiers 7 and 8, as amended. The proposed changes to the tiers' criteria are designed as an incentive to any and all Members interested in meeting the tier criteria to submit additional Customer orders (with opportunities to achieve such tiers via crossing and non-crossing orders), or AIM Agency orders to the Exchange. Each will have the opportunity to submit the requisite order flow and will receive the applicable existing enhanced rebate or reduced fee if the tier criteria are met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for the proposed tiers. While the Exchange has no way of predicting with certainty how the proposed tiers will impact Member activity, the Exchange anticipates that approximately three or four Members will be able to compete for and achieve the amended criteria in each of Customer Volume Tier 1, 2, 3, and 4, and at least four Members will be able to compete for and achieve the amended criteria in each of Market Maker Volume Tier 7 and Tier 8. The Exchange also notes that the proposed tiers will not adversely impact any Member's pricing or their ability to qualify for other rebate tiers. Rather, should a Member not meet the proposed criteria for a tier, the Member will merely not receive the corresponding enhanced rebate or reduced fee. Furthermore, the existing rebate and fees will continue to uniformly apply to all Members that meet the required criteria, as amended, per each respective tier.

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 intramarket or intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional order flow to a public exchange, thereby

[16] *See e.g.,* MIAX Options Fee Schedule, Section 1(a)(i), which provides reduced fees (ranging from $0.03 to $0.30) for Market Maker orders that reach various percentage thresholds of volume; and Section 1(a)(iii), which provides certain credits (ranging from $0.00 to $0.28) for Customer orders, including agency orders submitted to an exchange auction, that reach various percentage thresholds; *and* Cboe BZX U.S. Options Exchange Fee Schedule, Footnote 1, Customer Penny Pilot Add Tiers; Footnote 6, Market Maker Penny Pilot Add Volume Tiers; Footnote 7, Market Maker Non-Penny Pilot Add Volume Tiers; and Footnote 12, Customer Non-Penny Pilot Add Volume Tier, all of which provide various tier with different, incrementally more difficult criteria, many of which are based on average volumes as a percentage of average OCV.

[17] *See i.e.,* Cboe EDGX U.S. Options Exchange Fee Schedule, Footnote 1, Customer Volume Tiers; and Footnote 2, Market Maker Volume Tiers.

[18] *See supra* note 16.

[19] *See supra* note 11.

promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [20]

The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed change applies to all Members equally in that all Members are eligible to achieve the tiers' proposed criteria, have a reasonable opportunity to meet the tiers' proposed criteria and will all receive the existing enhanced rebates or reduced fees if such criteria is met. Overall, the proposed change is designed to attract additional Customer and AIM Agency order flow to the Exchange. The Exchange believes that the modified tier criteria would incentivize market participants to strive to increase such order flow to the Exchange to meet the proposed criteria and, as a result, increase trading opportunities and attract further Market-Maker activity, which would further incentivize the provision of liquidity and continued order flow and improve price transparency on the Exchange. Greater overall order flow and pricing transparency benefits all market participants on the Exchange by generally providing more trading opportunities, enhancing market quality, and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem, which benefits all market participants.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 15 other options exchanges and off-exchange venues and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single options exchange has more than 18% of the market share.[21] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [22] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .''.[23] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [24] and paragraph (f) of Rule 19b–4 [25] 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. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2020–033 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–CboeEDGX–2020–033. 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

[20] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

[21] *See supra* note 3.

[22] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[23] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f).

office of the Exchange. 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–CboeEDGX–2020–033, and should be submitted on or before August 5, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15214 Filed 7–14–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89273; File No. SR–CboeBZX–2020–056]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change To Add the Consolidated Audit Trail Industry Member Compliance Rules to the List of Minor Rule Violations in Rules 8.15 and 25.3

July 9, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 8, 2020, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') proposes to add the Consolidated Audit Trail (''CAT'') industry member compliance rules (''CAT Compliance Rules'') to the list of minor rule violations in Rules 8.15 and 25.3. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In order to implement the National Market System Plan Governing the Consolidated Audit Trail (the ''CAT NMS Plan'' or ''Plan'') the Exchange codified the CAT Compliance Rules in Rules 4.5 through 4.16.[3] The CAT NMS Plan was filed by the Plan Participants to comply with Rule 613 of Regulation NMS under the Exchange Act,[4] and each Plan Participant accordingly has adopted the same compliance rules as the Exchange's Rules 4.5 through 4.16. The common compliance rules adopted by each Plan Participant are designed to require industry members to comply with the provisions of the CAT NMS Plan, which broadly calls for industry members to record and report timely and accurate customer, order, and trade information relating to activity in NMS Securities and OTC Equity Securities.

Rule 8.15 provides for disposition of certain violations through assessment of fines in lieu of conducting a formal disciplinary proceeding. Rule 8.15.01, specifically, sets forth the list of specific BZX Equities Rules under which any Member, associated person of a Member, or registered or non-registered employee of a Member may be subject to a fine for violations of such Rules. Rule 25.3 provides the same for BZX Options Rule violations, under which an Options Member, associated person of an Options Member, or registered or non-registered employee of an Options Member may be subject to a fine for violations of such Rules. The Exchange proposes to amend Rule 8.15.01 and Rule 25.3 to add the CAT Compliance Rules in Rules 4.5 through 4.16 to the list of rules in Rule 8.15.01 and Rule 25.3 eligible for disposition pursuant to a minor fine; specifically, under proposed Rule 8.15.01(i) and proposed Rule 25.3(g).[5] Proposed Rule 8.15.01(i) and proposed Rule 25.3(g) each provide that for failures to comply with the Consolidated Audit Trail Compliance Rule requirements of Rules 4.5 through 4.16, the Exchange may impose a minor rule violation fine of up to $2,500. The Exchange may seek other disciplinary action for more serious violations.

The Exchange is coordinating with the Financial Industry Regulatory Authority, Inc. (''FINRA'') and other Plan Participants to promote harmonized and consistent enforcement of all the Plan Participants' CAT Compliance Rules. The Commission recently approved a Rule 17d–2 Plan under which the regulation of CAT Compliance Rules will be allocated among Plan Participants to reduce regulatory duplication for industry members that are members of more than one Participant (''common members'').[6] Under the Rule 17d–2 Plan, the regulation of CAT Compliance Rules with respect to common members that are members of FINRA is allocated to FINRA. Similarly, under the Rule 17d–2 Plan, responsibility for common members of multiple other Plan Participants and not a member of FINRA will be allocated among those other Plan Participants, including to the Exchange. For those non-common members who are allocated to BZX pursuant to the Rule 17d–2 Plan, the Exchange and FINRA have entered into a Regulatory Services Agreement (''RSA'') pursuant to which FINRA will assist the Exchange with conducting surveillance, investigation, examination, and enforcement activity in connection with

[26] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release Nos. 79927 (February 2, 2017), 82 FR 9874 (February 8, 2017) (SR–BatsBZX–2017–08); *and* 80256 (March 15, 2017), 82 FR 14526 (March 21, 2017) (Order Approving Proposed Rule Changes To Adopt Consolidated Audit Trail Compliance Rules).

[4] 17 CFR 242.613.

[5] FINRA's maximum fine for minor rule violations under FINRA Rule 9216(b) is $2,500. The Exchange will apply an identical maximum fine amount for eligible violations of Rules 4.5 through 4.16 to achieve consistency with FINRA and also amend its minor rule violation plan (''MRVP'') to include such fines. Like FINRA, the Exchange would be able to pursue a fine greater than $2,500 for violations of Rules 4.5 through 4.16 in a regular disciplinary proceeding or a letter of consent under Chapter 8 as appropriate. Any fine imposed in excess of $2,500 or not otherwise covered by Rule 19d–1(c)(2) of the Act would be subject to prompt notice to the Commission pursuant to Rule 19d–1 under the Act. As noted below, in assessing the appropriateness of a minor rule fine with respect to CAT Compliance Rules, the Exchange will be guided by the same factors that FINRA utilizes. *See* text accompanying notes 7–8 [sic], *infra.*

[6] *See* Securities Exchange Act Release No. 88366 (March 12, 2020), 85 FR 15238 (March 17, 2020).

the CAT Compliance Rules on the Exchange's behalf. The Exchange expects that the other exchanges will be entering into similar RSAs.

The Exchange notes that this proposal is based upon the FINRA filing to amend FINRA Rule 9217 in order to add FINRA's corresponding CAT Compliance Rules to FINRA's list of rules that are eligible for minor rule violation plan treatment.[7] The Exchange also notes that the New York Stock Exchange LLC (''NYSE'') submitted a filing to amend its Minor Rule Violation Plan (''MRVP'') to add its CAT Compliance Rules in a manner consistent with FINRA's proposal,[8] and other Plan Participants intend to submit the same. Thus, in order to achieve consistency with FINRA and the other Plan Participants, the Exchange proposes to adopt fines up to $2,500 in connection with minor rule fines for violations of the CAT Compliance Rules (Rules 4.5 through 4.16) in proposed Rules 8.15.01(i) and 25.3(g) under the Exchange's MRVP. In connection with FINRA's proposed amendment to FINRA Rule 9217 to make FINRA's CAT Compliance Rules MRVP eligible, FINRA has stated that it will apply the minor fines for CAT Compliance Rules in the same manner that FINRA has for its similar existing audit trail-related rules.[9] Accordingly, in order to promote regulatory consistency, the Exchange plans to do the same. Specifically, application of a minor fine with respect to CAT Compliance Rule violations will be guided by the same factors that FINRA references in its filing. However, more formal disciplinary proceedings may be warranted instead of minor rule dispositions in certain circumstances such as where violations prevent regulatory users of the CAT from performing their regulatory functions. Where minor rule dispositions are appropriate, the following factors help guide the determination of fine amounts:

- Total number of reports that are not submitted or submitted late;
- The timeframe over which the violations occur;
- Whether violations are batched;
- Whether the violations are the result of the actions of one individual or the result of faulty systems or procedures;
- Whether the firm has taken remedial measures to correct the violations;
- Prior minor rule violations within the past 24 months;
- Collateral effects that the failure has on customers; and
- Collateral effects that the failure has on the Exchange's ability to perform its regulatory function.[10]

Upon effectiveness of this rule change, the Exchange will publish a regulatory bulletin notifying its Members and/or Options Members of the rule change and the specific factors that will be considered in connection with assessing minor rule fines described above.

For the foregoing reasons, the Exchange believes that the proposed rule change will result in a coordinated, harmonized approach to CAT Compliance Rule enforcement across Plan Participants that will be consistent with the approach FINRA has taken with the CAT rules.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Minor rule fines provide a meaningful sanction for minor or technical violations of rules when the conduct at issue does not warrant stronger, immediately reportable disciplinary sanctions. The inclusion of a rule in the Exchange's MRVP does not minimize the importance of compliance with the rule, nor does it preclude the Exchange from choosing to pursue violations of eligible rules through a letter of consent if the nature of the violations or prior disciplinary history warrants more significant sanctions. Rather, the Exchange believes that the proposed rule change will strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities in cases where full disciplinary proceedings are unwarranted in view of the minor nature of the particular violation. The Exchange believes the option to impose a minor rule sanction gives the Exchange additional flexibility to administer its enforcement program in the most effective and efficient manner while still fully meeting the Exchange's remedial objectives in addressing violative conduct.[14] Specifically, the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because it will provide the Exchange the ability to issue a minor rule fine for violations of the CAT Compliance Rules in Rules 4.5 through 4.16 where a more formal disciplinary action may not be warranted or appropriate consistent with the approach of other Plan Participants for the same conduct.

In connection with the fine level specified in the proposed rule change, adding proposed Rules 8.15.01(i) and 25.3(g) to specifically provide that for violations of the CAT Compliance Rules in Rules 4.5 through 4.16 the Exchange may impose a fine not to exceed $2,500 would further the goal of transparency within the Exchange's rules. Adopting the same cap as FINRA for minor rule fines in connection with the CAT Compliance Rules would also promote regulatory consistency across self-regulatory organizations.

The Exchange further believes that the proposed amendments to Rule 8.15.01 and Rule 25.3 are consistent with Section 6(b)(6) of the Act,[15] which provides that members and persons associated with members shall be appropriately disciplined for violation of the provisions of the rules of the

[7] *See* Securities Exchange Act Release No. 88870 (May 14, 2020), 85 FR 30768 (May 20, 2020) (SR–FINRA–2020–013).

[8] *See* SR–NYSE–2020–51 (filed June 12, 2020).

[9] *See supra* note 7; *see* also FINRA Notice to Members 04–19 (March 2004) available at *https://www.finra.org/rules-guidance/notices/04-19* (providing specific factors used to inform dispositions for violations of OATS reporting rules).

[10] *See id.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] Pursuant to Rule 8.15(a) and (e) and Rule 25.3, the Exchange has the discretion to impose a fine in lieu of commencing a disciplinary proceeding for a violation that is minor in nature. Rule 8.15(e) states specifically that nothing in Rule 8.15 requires the Exchange to impose a fine pursuant to Rule 8.15 with respect to the violation of any Rule included in any such listing. Rule 25.3 states specifically that the Exchange is not required to proceed under said Rules as to any rule violation and may, whenever such action is deemed appropriate, commence a disciplinary proceeding under Chapter VIII (Discipline) rules as to any such violation.

[15] 15 U.S.C. 78f(b)(6).

exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction. As noted, the proposed rule change would provide the Exchange (both BZX Equities and BZX Options) the ability to sanction minor or technical violations of Rules 4.5 through 4.16 pursuant to the Exchange's rules.

Finally, the Exchange also believes that the proposed change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[16] Rule 8.15 does not preclude a Member, associated person of a Member, or registered or non-registered employee of a Member, and Rule 25.3 does not preclude an Options Member, associated person of an Options Member, or registered or non-registered employee of an Options Member, from contesting an alleged violation and receiving a hearing on the matter with the same procedural rights through a litigated disciplinary proceeding.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with making the CAT Compliance Rules in Rules 4.5 through 4.16 eligible for a minor rule fine disposition, thereby strengthening the Exchange's ability to carry out its oversight and enforcement functions and deter potential violative conduct. Also, as stated above, the proposed rule change is consistent with similar proposals recently filed by FINRA and NYSE, and other Plan Participants intend to submit the same.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. 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.

[16] 15 U.S.C. 78f(b)(7) and 78f(d).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2020–056 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2020–056. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2020–056 and should be submitted on or before August 5, 2020.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[17] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[18] which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act [19] which require that the rules of an exchange enforce compliance with, and provide appropriate discipline for, violations of Commission and Exchange rules. Finally, the Commission finds that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, as required by Rule 19d–1(c)(2) under the Act,[20] which governs minor rule violation plans.

As stated above, the Exchange proposes to add the CAT Compliance Rules to the list of minor rule violations in Rules 8.15 and 25.3 to be consistent with the approach FINRA has taken for minor violations of its corresponding CAT Compliance Rules.[21] The Commission has already approved FINRA's treatment of CAT Compliance Rules violations when it approved the addition of CAT Compliance Rules to FINRA's MRVP.[22] As noted in that order, and similarly herein, the Commission believes that Exchange's treatment of CAT Compliance Rules violations as part of its MRVP provides a reasonable means of addressing violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. However, the Commission expects that, as with FINRA, the Exchange will continue to conduct surveillance with

[17] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78f(b)(1) and 78f(b)(6).

[20] 17 CFR 240.19d–1(c)(2).

[21] As discussed above, the Exchange has entered into a Rule 17d–2 Plan and an RSA with FINRA with respect to the CAT Compliance Rules. The Commission notes that, unless relieved by the Commission of its responsibility, as may be the case under the Rule 17d–2 Plan, the Exchange continues to bear the responsibility for self-regulatory conduct and liability for self-regulatory failures, not the self-regulatory organization retained to perform regulatory functions on the Exchange's behalf pursuant to an RSA. *See* Securities Exchange Release No. 61419 (January 26, 2010), 75 FR 5157 (February 1, 2010) (SR–BATS–2009–031), note 93 and accompanying text.

[22] *See supra* note 7.

due diligence and make determinations based on its findings, on a case-by-case basis, regarding whether a sanction under the rule is appropriate, or whether a violation requires formal disciplinary action. Accordingly, the Commission believes the proposal raises no novel or significant issues.

For the same reasons discussed above, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[23] for approving the proposed rule change prior to the thirtieth day after the date of publication of the notice of the filing thereof in the **Federal Register**. The proposal merely adds the CAT Compliance Rules to the Exchange's MRVP and harmonizes its application with FINRA's application of CAT Compliance Rules under its own MRVP. Accordingly, the Commission believes that a full notice-and-comment period is not necessary before approving the proposal.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act [24] and Rule 19d–1(c)(2) thereunder,[25] that the proposed rule change (SR–CboeBZX–2020–056) be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15210 Filed 7–14–20; 8:45 am]

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[23] 15 U.S.C. 78s(b)(2).

[24] 15 U.S.C. 78s(b)(2).

[25] 17 CFR 240.19d–1(c)(2).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89269; File No. SR–DTC–2020–009]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Clearing Agency Risk Management Framework

July 9, 2020.

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 July 7, 2020, The Depository Trust Company (''DTC'') 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 clearing agency. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to the Clearing Agency Risk Management Framework (''Risk Management Framework'' or ''Framework'') of DTC and its affiliates, National Securities Clearing Corporation (''NSCC'') and Fixed Income Clearing Corporation (''FICC,'' and together with NSCC and DTC, the ''Clearing Agencies''). Specifically, the proposed rule change would (1) include a description of a set of policies that addresses the Clearing Agencies' compliance with Rule 17Ad–22(e)(22) of the Standards for Covered Clearing Agencies (''Standards''), under the Act,[5] (2) update the Risk Management Framework to reflect recent changes to certain processes and other matters described in the Framework, and changes to the status of documents identified in the Framework; and (3) clarify the descriptions of certain matters within the Framework to improve comprehensiveness and correct errors, as further described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency 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

1. Purpose

The Clearing Agencies adopted the Risk Management Framework [6] to provide an outline for how each of the Clearing Agencies (i) maintains a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities; (ii) comprehensively manages legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by it; (iii) identifies, monitors, and manages risks related to links it establishes with one or more clearing agencies, financial market utilities, or trading markets; and (iv) meets the requirements of its participants and the markets it serves efficiently and effectively. In this way, the Risk Management Framework currently supports the Clearing Agencies' compliance with Rules 17Ad–22(e)(1), (3), (20) and (21) of the Standards,[7] as described in the Initial Filing. In addition to setting forth the manner in which each of the Clearing Agencies addresses these requirements, the Risk Management Framework also contains a section titled ''Framework Ownership and Change Management'' that, among other matters, describes the Framework ownership and the required governance process for review and approval of changes to the Framework. In connection with the annual review and approval of the Framework by the Board of Directors of each of NSCC, DTC and FICC (each a ''Board'' and collectively, the ''Boards''), the Clearing Agencies are proposing to make certain revisions to the Framework.

The proposed changes would add a new Section 4.4 to describe a policy and a communication standard document that support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22), which requires the Clearing Agencies to establish, implement, maintain and enforce written policies and procedures reasonably designed to use, or at a minimum accommodate, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing, and settlement.[8]

The proposed changes would also update the Risk Management Framework to reflect (1) a change to the name of the Vendor Risk Management group to the Third Party Risk Management group; (2) a change to the format of the Balanced Business Scorecard, which is an internal performance management tool used to measure the effectiveness of various aspects of the operations of The Depository Trust & Clearing Corporation (''DTCC'') and its subsidiaries, including the Clearing Agencies; and (3) the filing

[5] 17 CFR 240.17Ad–22(e)(22).

[6] *See* Securities Exchange Act Release No. 81635 (September 15, 2017), 82 FR 44224 (September 21, 2017) (SR–DTC–2017–013; SR–NSCC–2017–012; SR–FICC–2017–016) (''Initial Filing'').

[7] 17 CFR 240.17Ad–22(e)(1), (3), (20) and (21).

[8] 17 CFR 240.17Ad–22(e)(22).

of certain documents identified in the Framework, pursuant to Section 19(b)(1) of the Act,[9] and the rules thereunder, and Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled the Payment, Clearing, and Settlement Supervision Act of 2010,[10] and the rules thereunder (collectively, ''Filing Requirements''), as described in greater detail below.

The proposed changes would also clarify and enhance the descriptions in the Risk Management Framework to (1) identify the requirement of Rule 17Ad–22(e)(3)(i) under the Act that the Framework be reviewed and approved by the Boards on an annual basis; [11] (2) identify the role of the DTCC Legal Department in supporting the management of legal risks that arise in or are borne by the Clearing Agencies; (3) enhance the description of the DTCC Risk Department as ''Second Line of Defense,'' (4) enhance the description of the DTCC Internal Audit Department as ''Third Line of Defense;'' (5) enhance the description of a policy relating to the establishment and governance of internal management committees; (6) enhance the description of the processes designed to maintain comprehensive policies, procedures and other documents; (7) clarify that certain activities described in the Framework that relate to the public disclosure of material information, including market data, address the Clearing Agencies' compliance with Rule 17Ad–22(e)(23) under the Act; [12] (8) enhance the description of the management of systemic risks by describing the role of the Systemic Risk Council; (9) correct a sentence by removing an unnecessary phrase; and (10) enhance the descriptions of certain actions by removing the indication that the Clearing Agencies have discretion in engaging in those actions.

Finally, the proposed changes would correct an error in the Risk Management Framework to identify the Audit Committees of the Boards as the committees to which the DTCC Internal Audit Department has a direct reporting line. Each of these proposed changes is described below.

i. Proposed Amendments To Describe Policies That Address Compliance With Rule 17Ad–22(e)(22)

First, the proposed changes would add a new Section 4.4 to the Framework to describe a policy maintained by the Clearing Agencies to use and accommodate relevant internationally accepted communication procedures and standards to facilitate efficient payment, clearing, and settlement, to support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22).[13]

The policy describes how the communication standards and data formats that are currently used by the Clearing Agencies for payment, clearing, and settlement are regarded as accepted industry standards for transactions processed through the Clearing Agencies. The policy also provides that the Clearing Agencies would accommodate new industry standards that are considered internationally accepted communication procedures and standards. The new Section 4.4 would also state that the Clearing Agencies maintain a communication standard document that supports this policy.

The Clearing Agencies are proposing to amend the Risk Management Framework to adopt a new Section 4.4 that would describe these documents, which support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22).[14]

ii. Proposed Amendments To Update the Framework

Second, the proposed changes would update the Risk Management Framework to reflect recent developments with respect to certain processes and other matters described in the Framework, and changes to the status of documents described in the Framework, as described below.

1. Proposed Change To Identify Third Party Risk Management

Section 4 of the Risk Management Framework outlines ways in which each of the Clearing Agencies manages certain risks that arise in or are borne by it. Specifically, Section 4.2 describes the management of risks related to material interdependencies and external links that may be established by the Clearing Agencies. The Clearing Agencies represent that management of risks presented by vendors and other material service providers is guided by a function within the Operational Risk Management group within the Group Chief Risk Office . This function was previously referred to as ''Vendor Risk Management.'' While the role and responsibilities of this risk management function have not changed, its name has recently been changed to ''Third Party Risk Management'' to clarify that the function covers any material third party service provider that provides a service to a DTCC entity.

The Clearing Agencies are proposing to amend Section 4.2.1 of the Risk Management Framework to reflect this name change and to clarify that the function covers any material third party service provider that provides a service to a DTCC entity by adding ''Third Party'' as a new defined term. The Clearing Agencies are also proposing to identify the existing policy and procedure that is maintained to manage these risks.

2. Proposed Change to Description of Balanced Business Scorecard

Section 4.3 of the Risk Management Framework addresses certain processes implemented by the Clearing Agencies in order to be efficient and effective in meeting the requirements of their respective participants and the markets they serve.[15] One of the methods the Clearing Agencies use to meet these requirements is the periodic creation of a Balanced Business Scorecard, which provides insight into the effectiveness of the Clearing Agencies' operations, information technology service levels, financial performance, human capital, and their respective participants' experience.

Previously, a Balanced Business Scorecard (referred to as the ''Core Balance Business Scorecard'') was created for the Clearing Agencies, and a separate Balanced Business Scorecard was created for the other subsidiaries of DTCC. Recently, these two tools merged, and only one Balanced Business Scorecard (now referred to as the ''DTCC Balanced Business Scorecard'') is created, which addresses DTCC and each of its subsidiaries, including each of the Clearing Agencies. While the new, enterprise-wide Balanced Business Scorecard reports its conclusions on a less granular, enterprise-wide basis, it is created using the same set of metrics as the legacy Clearing Agencies version. Therefore, the Balanced Business Scorecard continues to support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(21) under the Act.[16] The Balanced Business Scorecard now reports those metrics in the context of the DTCC enterprise, at a less granular level.

The Clearing Agencies are proposing to amend Section 4.3 of the Risk Management Framework to reflect the change in format of the Balanced Business Scorecard described above.

[9] 15 U.S.C. 78s(b)(1).

[10] 12 U.S.C. 5465(e)(1).

[11] 17 CFR 240.17Ad–22(e)(3)(i).

[12] 17 CFR 240.17Ad–22(e)(23).

[13] 17 CFR 240.17Ad–22(e)(22).

[14] *Id.*

[15] Such processes support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(21) under the Act. 17 CFR 240.17Ad–22(e)(21).

[16] *Id.*

3. Proposed Change to Description of Certain Documents To Reflect Filing Pursuant to Filing Requirements

Following the adoption of the Risk Management Framework, certain documents that are identified in the Framework were filed pursuant to the Filing Requirements. The Clearing Agencies are proposing to revise the descriptions of these documents to reflect this change.

Section 3.3 of the Framework describes certain frameworks that are maintained by the Clearing Agencies and provide an outline for certain policies and procedures that address, in whole or in part, the management of operational, liquidity, credit, market, collateral, and other risks. This section identified five such frameworks, the Clearing Agency Operational Risk Management Framework, the Clearing Agency Liquidity Risk Management Framework, the Clearing Agency Securities Valuation Framework, the Clearing Agency Stress Testing Framework, and the Clearing Agency Model Risk Management Framework. Each of these frameworks has been filed pursuant to the applicable Filing Requirements and adopted by the Clearing Agencies.[17] The Clearing Agencies are proposing to update Section 3.3 to reflect this change.

Section 5 of the Risk Management Framework describes the plans that are maintained by each of the Clearing Agencies for their recovery or orderly wind-down (''R&W Plans''). The R&W Plans were still in development when the Framework was adopted, but have since been finalized, approved by the Boards, filed pursuant to the Filing Requirements, and adopted by the Clearing Agencies.[18] Therefore, the Clearing Agencies are proposing to update Section 5 to reflect these developments, and to describe the ongoing governance of the R&W Plans.

iii. Proposed Amendments To Clarify, Enhance, and Correct Descriptions in the Framework

Finally, the proposed changes would enhance the descriptions of certain matters within the Risk Management Framework to improve its clarity and comprehensiveness and correct an error, as described below.

1. Proposed Change To Correct Annual Approval of Framework by Boards

Section 2 of the Risk Management Framework addresses the Framework's ownership and change management. This section currently states that the Framework should be reviewed by the document owner no less frequently than annually but does not specifically identify the requirement that the Framework also be approved by the Boards on an annual basis. The Clearing Agencies are proposing to correct the Framework to include the requirement that the Framework be approved by the Boards, or a duly authorized committee of the Boards, annually.

Rule 17Ad–22(e)(3) under the Act requires that the Clearing Agencies maintain a sound risk management framework for comprehensively managing the risks that arise in or are borne by the Clearing Agencies, including investment and custody risks.[19] Rule 17Ad–22(e)(3)(i) under the Act requires that the risk management policies, procedures, and systems that are maintained in compliance with Rule 17Ad–22(e)(3) be subject to review on a specified periodic basis and be approved by the Boards annually.[20] As stated above, the Framework provides an outline for how each of the Clearing Agencies comprehensively manages legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by it, as required by Rule 17Ad–22(e)(3) under the Act.[21] Therefore, the Risk Management Framework is reviewed and approved by the Boards annually, as required by Rule 17Ad–22(e)(3)(i) under the Act.[22]

The Clearing Agencies are proposing to amend Section 2 of the Framework to state that the Framework shall be approved by the Boards, or a duly authorized committee of the Boards, annually. The proposed change would correct the Framework to include this requirement, which is aligned with the applicable requirements of Rule 17Ad–22(e)(3)(i) under the Act.[23]

2. Proposed Change To Identify DTCC Legal Department's Role in Management of Clearing Agencies' Legal Risks

Section 3.1 of the Risk Management Framework describes the ''three lines of defense'' approach adopted by each of the Clearing Agencies for identifying, assessing, measuring, monitoring, mitigating, and reporting the risks that arise in or are borne by it. Currently, this section outlines the role of each line of defense, and specifically describes the roles of the DTCC Risk Department (''Risk Department'') and DTCC Internal Audit Department (''Internal Audit'') within this risk management approach. The DTCC Legal Department (''Legal Department'') also plays a particular role in the three lines of defense approach by supporting each line of defense in the management of legal risks.

While the Legal Department is currently identified as part of the control functions that form the second line of defense in Section 3.1.2, its particular role is not separately described. Therefore, the Clearing Agencies are proposing to update the introduction of Section 3.1 to state that the Legal Department supports each line of defense in the management of legal risks. This proposed change would more clearly describe the particular role of the Legal Department in this risk management approach.

3. Proposed Change To Enhance Description of DTCC's Risk Department as ''Second Line of Defense'' in Risk Management

As stated above, Section 3.1 of the Risk Management Framework describes the ''three lines of defense'' approach to risk management adopted by the Clearing Agencies. Section 3.1.2 describes the particular role of the Risk Department as the second line of defense within this risk management approach. The Clearing Agencies are proposing to amend this Section 3.1.2 to enhance the description of the Risk Department's role, including by providing details relating to the role of the Operational Risk Management group within the Risk Department. The proposed amendments would describe how the Operational Risk Management group addresses and escalates incidents based on a risk rating of those incidents. In addition, the proposed change would

[17] *See* Securities Exchange Act Release Nos. 81745 (September 28, 2017), 82 FR 46332 (October 4, 2017) (SR–DTC–2017–014; SR–NSCC–2017–013; SR–FICC–2017–017) (Operational Risk Management Framework); 82377 (December 21, 2017), 82 FR 61617 (December 28, 2017) (SR–DTC–2017–004; SR–NSCC–2017–005; SR–FICC–2017–008) (Liquidity Risk Management Framework); 82006 (November 2, 2017), 82 FR 51892 (November 8, 2017) (SR–DTC–2017–016; SR–NSCC–2017–016; SR–FICC–2017–020) (Securities Valuation Framework); 82368 (December 19, 2017), 82 FR 61082 (December 26, 2017) (SR–DTC–2017–005; SR–FICC–2017–009; SR–NSCC–2017–006) (Stress Testing Framework); and 81485 (August 25, 2017), 82 FR 41433 (August 31, 2017) (SR–DTC–2017–008; SR–FICC–2017–014; SR–NSCC–2017–008) (Model Risk Management Framework).

[18] *See* Securities Exchange Act Release Nos. 83972 (August 28, 2018), 83 FR 44964 (September 4, 2018) (SR–DTC–2017–021); 83953 (August 27, 2018), 83 FR 44381 (August 30, 2018) (SR–DTC–2017–803); 83974 (August 28, 2018), 83 FR 44988 (September 4, 2018) (SR–NSCC–2017–017); 83955 (August 27, 2018), 83 FR 44340 (August 30, 2018) (SR–NSCC–2017–805); 83973 (August 28, 2018), 83 FR 44942 (September 4, 2018) (SR–FICC–2017–021); 83954 (August 27, 2018), 83 FR 44361 (August 30, 2018) (SR–FICC–2017–805).

[19] 17 CFR 240.17Ad–22(e)(3).

[20] 17 CFR 240.17Ad–22(e)(3)(i).

[21] 17 CFR 240.17Ad–22(e)(3).

[22] 17 CFR 240.17Ad–22(e)(3)(i).

[23] *Id.*

clarify the description relating to the procedures, processes, tools, mechanisms, analyses, and testing controls employed by the Risk Department and indicate that such procedures, etc. are subject to the parameters set forth in Section 3.3, which discusses the Filing Requirements and document standards relating to policies, procedures, frameworks and certain related documents. In addition, the Clearing Agencies are proposing to add a defined term in Section 3.1 to reflect that the Risk Department refers to the Risk Department of DTCC. The proposed changes would more clearly describe the particular role of the Risk Department in this risk management approach.

4. Proposed Change To Enhance Description of DTCC's Internal Audit Department as ''Third Line of Defense'' in Risk Management

Section 3.1.3 of the Risk Management Framework describes the particular role of Internal Audit as the third line of defense within the risk management approach. The Clearing Agencies are proposing to amend this Section 3.1.3 to enhance the description of Internal Audit's role, including by providing a clearer description of the responsibilities of Internal Audit, making grammatical changes to certain descriptions to improve readability, and removing references to Internal Audit as providing an advisory role to the Clearing Agencies. By removing references to advisory services, the proposed changes would conform the Risk Management Framework to the charter of the Audit Committees of the Boards, where similar changes have been made to reinforce the group's role as the third line of defense in risk management and its independence and objectivity in the performance of assurance services. In addition, the Clearing Agencies are proposing to add a defined term in Section 3.1 to clarify that Internal Audit refers to the Internal Audit Department of DTCC.

5. Proposed Change To Enhance Description of Policy Regarding Management Committees and Oversight

Section 3.2 of the Risk Management Framework states that a set of senior management committees provides oversight of various aspects of the Clearing Agencies' activities, including risk management, and describes the policy that sets forth the requirements for establishing and governing these committees. The Clearing Agencies are proposing to amend Section 3.2 by including a reference to the described document and providing a clearer and more complete description of the contents of this policy and the ongoing governance requirements of senior management committees. The proposed changes would not make any substantive changes to this description.

6. Proposed Change To Enhance Description of Management of Policies, Procedures, and Other Documents

Section 3.3.1 of the Risk Management Framework states that the Clearing Agencies maintain comprehensive policies and procedures designed to identify, measure, monitor and manage the risks that arise in or are borne by the Clearing Agencies, and describes a set of standards the Clearing Agencies have established for creating and managing these documents. The Clearing Agencies are proposing to amend the description of these standards. The proposed amendments to Section 3.3.1 would re-word the descriptions of these standards by, for example, more clearly describing the governance of these documents, how these standards provide guidance on reviews of these documents by document owners, and the role of the document owners in adhering to these standards. The proposed changes would not make any substantive changes to this description.

7. Proposed Change To Clarify Regulatory Basis of Certain Public Disclosures

Section 4.1 of the Risk Management Framework states that the Clearing Agencies provide their respective participants with information and incentives to enable them, and, through them, their customers, to understand, monitor, manage, and contain the risks they pose to the respective Clearing Agencies, and identifies some of the tools the Clearing Agencies provide to their participants to facilitate this understanding. The Clearing Agencies are proposing to amend Section 4.1 to make clarifying edits.

First, the proposed amendments would clarify that the tools and activities described in Section 4.1 support the Clearing Agencies' compliance with Rule 17Ad–22(e)(23) under the Act.[24] Rule 17Ad–22(e)(23) requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for publicly disclosing relevant basic data on transaction volume and values, and a comprehensive public disclosure that describes their material rules, policies, and procedures regarding their legal, governance, risk management, and operating framework, accurate in all material respects at the time of publication.[25] Certain matters described in Section 4.1 of the Framework, including the publication of disclosure frameworks and quantitative disclosures (described below), support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(23).[26] Therefore, the Clearing Agencies would update the introduction to Section 4.1, and make a conforming change to Section 1 of the Framework, to refer to Rule 17Ad–22(e)(23).[27]

Second, the proposed amendments would correct a statement in Section 4.1 of the Framework regarding the disclosure frameworks posted to the DTCC website for each of the Clearing Agencies on a biennial basis, which provide a comprehensive description of how the businesses and operations of the Clearing Agencies reflect the Principles for financial market infrastructures, issued by the Committee on Payment and Settlement Systems (''CPSS'') and the Technical Committee of the International Organization of Securities Commissions (''IOSCO'').[28] These disclosure frameworks also address how the businesses and operations of the Clearing Agencies reflect the Standards. Therefore, the Clearing Agencies would correct this statement in Section 4.1 regarding the scope of the disclosure frameworks by also referring to the Standards.

Finally, the proposed amendments would correct a statement in Section 4.1 of the Framework regarding the quantitative disclosures that are posted to the DTCC website on a quarterly basis, which disclose certain quantitative data and other information as set out in the Public quantitative disclosure standards for central counterparties published by CPMI and IOSCO.[29] Currently, Section 4.1 states that these disclosures relate to the Clearing Agencies. However, these disclosures are only required for central counterparties and, as such, only relate to NSCC and FICC, and not DTC. The Clearing Agencies would correct this error by replacing ''Clearing Agencies''

[24] 17 CFR 240.17Ad–22(e)(23).

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] CPSS and the Technical Committee of IOSCO, Principles for financial market infrastructures (April 16, 2012), *available at http://www.bis.org/cpmi/publ/d101a.pdf.* In 2014, CPSS became the Committee on Payments and Market Infrastructures (''CPMI'').

[29] CPMI and the Board of IOSCO, Public quantitative disclosure standards for central counterparties (February 26, 2015), *available at https://www.iosco.org/library/pubdocs/pdf/IOSCOPD475.pdf.*

with ''NSCC and FICC, as central counterparties'' in Section 4.1 of the Framework.

8. Proposed Change To Enhance Description of Governance of Systemic Risk Management

The proposed change would enhance the description of the governance of systemic risk management in Section 4.2.1 by including a description of the Systemic Risk Council, the frequency of this Council's meetings, and stating that matters discussed at these meetings may be escalated to the Management Risk Committee or the Board Risk Committee when appropriate. The proposed changes would improve the descriptions in the Framework by providing additional details regarding the governance of systemic risk management.

9. Proposed Change To Enhance Description of Management of Risk Related to Other External Links

The proposed change would enhance the description of the management of risks related to external links in Section 4.2.2 by identifying a policy and a procedure that are maintained by the Clearing Agencies to govern this process. The proposed change would improve the disclosures in the Framework by providing a clear reference to these documents.

10. Proposed Change To Remove Unnecessary Phrase

The proposed change would remove an unnecessary phrase '', is set forth in'' that is incorrectly at the end of a sentence in Section 1 of the Framework.

11. Proposed Change To Rephrase Sentences That Incorrectly Indicate Discretion in Taking Certain Actions

The proposed change would rephrase four sentences in the Framework that currently indicate the action described is discretionary. First, the proposed change would rephrase a statement in Section 4.2.1 to remove the indication that the Clearing Agencies have discretion to not manage risks related to participants and settlement banks. Second, the proposed change would rephrase a statement in Section 4.2.1 to remove the indication that the Clearing Agencies have discretion to not maintain policies, procedures or templates relating to the management of third-party risks. Third, the proposed change would rephrase a statement in Section 4.2.2 to remove the indication that the General Counsel's Office has discretion in reviewing certain key link arrangements. Finally, the proposed change would rephrase a statement in Section 5 to remove the indication that the Clearing Agencies have discretion to not maintain policies and procedures governing the development and maintenance of R&W Plans.

12. Proposed Change To Correct Error Regarding Reporting Line of DTCC Internal Audit Department

The Clearing Agencies are proposing a change to the Framework to correct an error in Section 3.1.3, which currently states Internal Audit has a direct reporting line to the Risk Committees of the Boards. This statement is incorrect, as Internal Audit has a direct reporting line to the Audit Committees of the Boards. The Clearing Agencies would correct this error by making a minor revision to Section 3.1.3 of the Framework. In addition, the Clearing Agencies are proposing to change references of ''Audit Committee'' to ''Audit Committees'' to reflect that each of the Boards has an audit committee.

2. Statutory Basis

The Clearing Agencies believe that the proposed changes are consistent with Section 17A(b)(3)(F) of the Act [30] and Rules 17Ad–22(e)(22) and (e)(23) promulgated under the Act,[31] for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.[32] The proposed changes would (1) add a description of how the Clearing Agencies address compliance with Rule 17Ad–22(e)(22), (2) update the descriptions of certain matters in the Risk Management Framework, and (3) clarify and correct other statements within the Framework, as described above. By addressing the Clearing Agencies' compliance with Rule 17Ad–22(e)(22), creating clearer, updated descriptions and correcting errors, the Clearing Agencies believe that the proposed changes would make the Risk Management Framework more effective in providing an overview of the important risk management activities of the Clearing Agencies, as described therein.

As described in the Initial Filing, the risk management functions described in the Risk Management Framework allow the Clearing Agencies to continue to promote the prompt and accurate clearance and settlement of securities transactions, and continue to assure the safeguarding of securities and funds which are in their custody or control or for which they are responsible notwithstanding the default of a member of an affiliated family. The proposed changes to describe policies that address to the Clearing Agencies' communication standards and improve the clarity and accuracy of the descriptions of risk management functions within the Framework would assist the Clearing Agencies in carrying out these risk management functions. Therefore, the Clearing Agencies believe these proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[33]

Rule 17Ad–22(e)(22) under the Act requires that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to use, or at a minimum accommodate, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing, and settlement.[34] The Framework would describe a policy maintained by the Clearing Agencies that (1) identifies the communication standards and data forms used by the Clearing Agencies for payment, clearing and settlement that are regarded as accepted industry standards for transactions processed through the Clearing Agencies, and (2) provides that the Clearing Agencies would accommodate relevant internationally accepted communication procedures and standards when new industry standards are introduced. By describing the Clearing Agencies' use of accepted industry communication standards and their policy of supporting new industry standards when introduced, this policy, and a supporting communication standards document, both support the Clearing Agencies' compliance with Rule 17Ad–22(e)(22).[35] Therefore, the Clearing Agencies believe that the proposed rule change to include this policy in the Risk Management Framework is consistent with Rule 17Ad–22(e)(22).[36]

Rule 17Ad–22(e)(23) under the Act requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for publicly disclosing relevant basic data on transaction volume and values, and a comprehensive public

[30] 15 U.S.C. 78q–1(b)(3)(F).

[31] 17 CFR 240.17Ad–22(e)(22) and (e)(23).

[32] 15 U.S.C. 78q–1(b)(3)(F).

[33] *Id.*

[34] 17 CFR 240.17Ad–22(e)(22).

[35] *Id.*

[36] *Id.*

disclosure that describes their material rules, policies, and procedures regarding their legal, governance, risk management, and operating framework, accurate in all material respects at the time of publication.[37] Section 4.1 of the Framework currently describes how the Clearing Agencies provide their respective participants with information and incentives to enable them, and, through them, their customers, to understand, monitor, manage and contain the risks they pose to the respective Clearing Agencies, and identifies some of the tools the Clearing Agencies provide to their participants to facilitate this understanding. The proposed rule change would revise Section 4.1 of the Framework to state that those tools and activities support the Clearing Agencies' compliance with Rule 17Ad–22(e)(23) under the Act.[38] By describing these actions, including the publication of disclosure frameworks and quantitative disclosures, the Clearing Agencies believe that the proposed change to the Risk Management Framework is consistent with Rule 17Ad–22(e)(23).[39]

(B) Clearing Agency's Statement on Burden on Competition

The Clearing Agencies do not believe that the proposed changes to the Framework described above would have any impact, or impose any burden, on competition. As described above, the proposed rule changes would improve the comprehensiveness of the Framework by including a description of the Clearing Agencies' compliance with Rule 17Ad–22(e)(22) under the Act and would also improve the clarity and accuracy of the descriptions of certain matters within the Framework. Therefore, the proposed changes are technical and non-material in nature, relating mostly to the operation of the Framework rather than the risk management functions described therein. As such, the Clearing Agencies do not believe that the proposed rule changes would have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[40] and Rule 19b–4(f)(6) thereunder.[41]

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–DTC–2020–009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–DTC–2020–009. 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 DTC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–DTC–2020–009 and should be submitted on or before August 5, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15206 Filed 7–14–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89268; File No. SR–LCH SA–2020–002]

Self-Regulatory Organizations; LCH SA; Notice of Filing of Proposed Rule Change, as Modified by Amendment No. 1, Relating to Introduction of Clearing of the New Markit iTraxx MSCI ESG Screened Europe Index Contracts

July 9, 2020.

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 June 26, 2020, Banque Centrale de Compensation, which conducts business under the name LCH SA (''LCH SA''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II and III below, which Items have been prepared primarily by LCH SA. On July 8, 2020, LCH SA filed Amendment No. 1 to the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule change as modified by

[37] 17 CFR 240.17Ad–22(e)(23).

[38] *Id.*

[39] *Id.*

[40] 15 U.S.C. 78s(b)(3)(A).

[41] 17 CFR 240.19b–4(f)(6).

[42] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Amendment No. 1 from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

Banque Centrale de Compensation, which conducts business under the name LCH SA (''LCH SA''), is proposing the Amendment 1 to the filing LCH SA–2020–002 in order to (i) explain the few minor clarifications made below with respect to both sections 3.2 and 3.8 and also remove (ii) the non-relevant change made to the Legal Entity Identifier Margin in section 6.2 of its Reference Guide: CDS Margin Framework.

LCH SA is proposing to amend its Reference Guide: CDS Margin Framework to permit the clearing of iTraxx MSCI ESG Screened Europe index contracts. As further detailed below, LCH SA is also making a number of other minor changes unrelated to the clearing of iTraxx MSCI ESG Screened Europe index CDS transactions.

The text of the proposed rule change has been annexed as Exhibit 5.[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, LCH SA 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. LCH SA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of these statements.

A. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

LCH SA is proposing to amend its Reference Guide: CDS Margin Framework in order to introduce clearing of the iTraxx MSCI ESG Screened Europe index CDS transactions.

Markit launched the iTraxx MSCI ESG Screened Europe Index (''iTraxx ESG Index'') on March 20th, 2020. This index is a subset of the iTraxx Europe Main index. The constituents of the iTraxx MSCI ESG Screened Europe index must meet various Corporate Responsibility Criteria. The first series that launched on March 20th, 2020 (Series 33) has 81 constituents, all are constituents of the iTraxx Europe Main index Series 33.

To permit participants to submit for clearing iTraxx ESG Index contracts, LCH SA needs to modify its Reference Guide: CDS Margin Framework.

In this regard, LCH SA has made the following changes to the Reference Guide: CDS Margin Framework:

(i) Removing references to specific indices in the document and replacing them with a generic reference to an index in sections 2.3.3, and 3.8.1.3,

(ii) removing the fixed 24% value and changing the spread shock formula for it to be applicable more generically to both iTraxx Main index and any of its sub index including financial Single Names.

Clearing of the new iTraxx ESG Index contracts will not require any other changes to LCH SA CDSClearing Rule Book or risk management framework or other policies and procedures constituting rules within the meaning of the Securities Exchange Act of 1934 (''Act'').

LCH SA is also taking this opportunity to make the following changes which are unrelated to the clearing of iTraxx MSCI ESG Screened Europe index CDS transactions;

(i) removing the list of Dealers in section 2.3.3 as LCH SA may contact a broader list of Dealers than that currently listed in this section;

(ii) correction in section 3.2 of a typing error to confirm the relevant application of the Wrong Way Risk Margin to Options;

(iii) correction of the worst 5 day P&L value per date and the worst P&L value aggregated per date formulae in section 3.5.6. to reflect the fact that the same date is selected to calculate the portfolio P&L for all contracts in the portfolio;

(iv) the 9M curve has been removed from the Interest Rate Risk Margin calculation in section 3.6, reflecting the change of interest rate curve imposed by ISDA within the framework of the risk-free rate benchmark review;

(v) clarification under section 3.8 that the short charge is covering the risk that at least one entity defaults;

(vi) the Wrong Way Risk formulae in section 3.8.1 were incomplete, the second value ''0'' to be used to derive the maximum resulting from these formulae has been added.

At the request of LCH SA Risk Model Validation team so that the CDSClear risk framework can be better assessed, LCH SA is making the relevant clarifications specified under the below subsections (vii) to (xii):

(vii) Adding a note in section 3.8.1.2 that clarifies that the recovery rate for a Senior Unsecured Debt (Corporate/Financial)/ Foreign Currency Sovereign Debt (Government) (SNRFOR) and Senior Loss Absorbing Capacity (SNRLAC) seniorities are considered as if they were two different instruments;

(viii) adding a note in section 3.8.2 to explicit the calibration of the shocks displayed in the table;

(ix) adding a note in section 4.1.3.1 to describe the parameters used in the formula;

(x) the Average Liquidity Score formula has been amended and a note inserted in order to clarify which days are used to compute the Average Liquidity Score;

(xi) the net notional for the index basis product p, tenor t used in the formula for the sum of the 5Y equivalent notional has been amended to an absolute value;

(xii) in view of the upcoming supervisory/ regulatory transition from the Euro Overnight Index Average (EONIA) to the new Euro Short-Term Rate (ESTER or €STR) and the Fed Funds to the Secured Overnight Financing Rate (SOFR), references to the interest rate applied to the Price Alignment Interest in section 5.2 have been removed.

2. Statutory Basis

LCH SA has determined that Proposed Rule Change is consistent with the requirements of Section 17A of the Securities Exchange Act (''Act'') [4] and regulations thereunder applicable to it. Section 17A(b)(3)(F) of the Act requires, *inter alia,* that the rules of a clearing agency ''assure the safeguarding of securities and funds that are in its custody or control or for which it is responsible . . . and, in general, to protect investors and the public interest.'' [5]

LCH SA believes that acceptance of the new iTraxx ESG Index contracts, on the terms and conditions set out in the Rules, is consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by LCH SA, the safeguarding of securities and funds in the custody or control of LCH SA or for which it is responsible, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act. Indeed, the new iTraxx ESG Index contracts proposed for clearing are similar to the other European Indices contracts currently cleared by LCH SA CDSClear, and will be cleared pursuant to LCH SA's existing clearing arrangements and related financial safeguards, protections and risk management procedures.

Clearing of the iTraxx ESG Index contracts will also satisfy the relevant requirements of Rule 17Ad–22,[6] as set forth in the following discussion.

Margin Requirements. Rule 17Ad–22(e)(4) [7] requires LCH SA to effectively identify, measure, monitor, and manage its credit exposures to participants and

[3] All capitalized terms not defined herein have the same definition as the Rule Book, Supplement or Procedures, as applicable.

[4] 15 U.S.C. 78q–1.

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] 17 CFR 240.17Ad–22.

[7] 17 CFR 240.17Ad–22(e)(4).

those arising from its payment, clearing, and settlement processes. In terms of financial resources, LCH SA will apply its existing margin methodology—including its Wrong Way Risk margin framework—to the new iTraxx ESG Index, which are similar to the European indices currently cleared by LCH SA. LCH SA believes that this model will provide sufficient margin requirements to cover its credit exposure to its clearing members from clearing such contracts, consistent with the requirements of Rule 17Ad–22(e)(4).

Financial Resources. Rule 17Ad–22(e)(4)(i) [8] requires LCH SA to maintain sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence and to the extent not already maintained pursuant to paragraph (e)(4)(i), Rule 17Ad–22(e)(4)(ii) [9] requires LCH SA to maintain additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the two participant families that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions. LCH SA believes its Default Fund, under its existing methodology, will, together with the required margin, provide sufficient financial resources to support the clearing of the iTraxx ESG Index contracts, consistent with the requirements of Rule 17Ad–22(e)(4).

Operational Resources. Rule 17Ad–22(e)(3) [10] requires LCH SA to maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency. LCH SA believes that its existing operational and managerial resources will be sufficient for clearing of the iTraxx ESG Index contracts, consistent with the requirements of Rule 17Ad–22(e)(3), as this new index contract is substantially the same from an operational perspective as the existing index contracts.

LCH SA will also apply its existing default management policies and procedures for the iTraxx ESG Index contracts. LCH SA believes that these procedures allow for it to take timely action to contain losses and liquidity pressures and to continue meeting its obligations in the event of clearing member insolvencies or defaults in respect of the additional single names, in accordance with Rule 17Ad–22(e)(13).

The proposed change regarding the transition from EONIA which does not comply with the recently introduced EU Benchmarks Regulation to ESTER is intended to comply with this European Central Bank (ECB) initiative supported by regulators. Rule 17Ad–22(e)(1) [11] requires a covered clearing agency to provide for a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities in all relevant jurisdictions. Rule 17Ad–22(e)(2)(iii) [12] also requires to support the objectives of participants.

For all these reasons, LCH SA believes that the Proposed Rule Change is consistent with the requirements of Section 17A of the Act and the regulations thereunder, including the standards under Rule 17Ad–22.

B. Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[13] The iTraxx ESG Index contracts will be available to all LCH SA's CDSClear participants for clearing. The clearing of these new iTraxx ESG Index contracts by LCH SA does not preclude the offering of the iTraxx ESG Index contracts for clearing by other market participants. Accordingly, LCH SA does not believe that clearance of the new iTraxx ESG Index contracts will impose any burden on competition 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 rule change have not been solicited or received. LCH SA will notify the Commission of any written comments received by LCH SA.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–LCH SA–2020–002 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–LCH SA–2020–002. 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 LCH SA and on LCH SA's website at: *https://www.lch.com/resources/rules-and-regulations/proposed-rule-changes-0.* 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

[8] 17 CFR 240.17Ad–22(e)(4)(i).

[9] 17 CFR 240.17Ad–22(e)(4)(ii).

[10] 17 CFR 240.17Ad–22(e).

[11] 17 CFR 240.17Ad–22 (e)(1).

[12] 17 CFR 240.17Ad–22(e)(iii).

[13] 15 U.S.C. 78q–1(b)(3)(I).

to make available publicly. All submissions should refer to File Number SR–LCH SA–2020–002 and should be submitted on or before August 5, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15205 Filed 7–14–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33924; File No. 812–15051]

Aspiriant Defensive Allocation Fund and Aspiriant LLC

July 10, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application [1] for an order under sections 6(c) and 23(c)(3) of the Investment Company Act of 1940 (the ''Act'') for an exemption from rule 23c–3 under the Act.

SUMMARY OF APPLICATION: Applicants request an order under sections 6(c) and 23(c)(3) of the Act for an exemption from certain provisions of rule 23c–3 to permit certain registered closed-end investment companies to make repurchase offers on a monthly basis.

APPLICANTS: Aspiriant Defensive Allocation Fund (the ''Fund'') and Aspiriant LLC (the ''Adviser'').

FILING DATES: The application was filed on July 26, 2019 and amended on April 10, 2020.

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 by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on July 30, 2020, and should be accompanied by proof of service on the 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 at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Benjamin D. Schmidt, Aspiriant LLC, 111 East Kilbourne Avenue, Suite 1700, Milwaukee, WI 53202.

FOR FURTHER INFORMATION CONTACT: Stephan N. Packs, Senior Counsel, at (202) 551–6853, or David J. Marcinkus, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Fund is a Delaware statutory trust that filed for registration under the Act on October 22, 2019 as a diversified, closed-end management investment company that will be operated as an interval fund. The Adviser is a Delaware limited liability company and is registered as an investment adviser under the Investment Advisers Act of 1940. The Adviser serves as investment adviser to the Fund.

2. Applicants request that any relief granted also apply to any registered closed-end management investment company that operates as an interval fund pursuant to rule 23c–3 for which the Adviser or any entity controlling, controlled by, or under common control with the Adviser, or any successor in interest to any such entity,[2] acts as investment adviser (the ''Future Funds,'' and together with the Fund, the ''Funds,'' and each, individually, a ''Fund'').[3] The Fund's common shares are not offered or traded in the secondary market and are not listed on any exchange or quoted on any quotation medium.

3. Applicants request an order to permit each Fund to offer to repurchase a portion of its common shares at one-month intervals, rather than the three, six, or twelve-month intervals specified by rule 23c–3.

4. Each Fund will disclose in its prospectus and annual reports its fundamental policy to make monthly offers to repurchase a portion of its common shares at net asset value, less deduction of a repurchase fee, if any, as permitted by rule 23c–3(b)(1). The fundamental policy will be changeable only by a majority vote of the holders of such Fund's outstanding voting securities. Under the fundamental policy, the repurchase offer amount will be determined by the board of trustees of the applicable Fund (''Board'') prior to each repurchase offer. Each Fund will comply with rule 23c–3(b)(8)'s requirements with respect to its trustees who are not interested persons of such Fund, within the meaning of section 2(a)(19) of the Act (''Disinterested Trustees'') and their legal counsel. Each Fund will make monthly offers to repurchase not less than 5% of its outstanding shares at the time of the repurchase request deadline. The repurchase offer amounts for the then-current monthly period, plus the repurchase offer amounts for the two monthly periods immediately preceding the then-current monthly period, will not exceed 25% of the outstanding common shares of the applicable Fund.

5. Each Fund's fundamental policies will specify the means to determine the repurchase request deadline and the maximum number of days between each repurchase request deadline and the repurchase pricing date. Each Fund's repurchase pricing date normally will be the same date as the repurchase request deadline and pricing will be determined after close of business on that date.

6. Pursuant to rule 23c–3(b)(1), each Fund will repurchase shares for cash on or before the repurchase payment deadline, which will be no later than seven calendar days after the repurchase pricing date. The Fund (and any Future Fund) currently intends to make payment by the fifth business day or seventh calendar day (whichever period is shorter) following the repurchase pricing date. Each Fund will make payment for shares repurchased in the previous month's repurchase offer at least five business days before sending notification of the next repurchase offer. The Fund intends to, and a Future Fund may, deduct a repurchase fee in an amount not to exceed 2% from the repurchase proceeds payable to tendering shareholders, in compliance with rule 23c–3(b)(1).

7. Each Fund will provide common shareholders with notification of each repurchase offer no less than seven days

[14] 17 CFR 200.30–3(a)(12).

[1] The notice is being reissued solely because the original notice inadvertently was not published in the **Federal Register**.

[2] A successor in interest is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[3] All entities currently intending to rely on the requested relief have been named as applicants. Any entity that relies on the requested order in the future will do so only in accordance with the terms and conditions of the application.

and no more than fourteen days prior to the repurchase request deadline. The notification will include all information required by rule 23c–3(b)(4)(i). Each Fund will file the notification and the Form N–23c–3 with the Commission within three business days after sending the notification to its respective common shareholders.

8. The Funds will not suspend or postpone a repurchase offer except pursuant to the vote of a majority of its Trustees, including a majority of its Disinterested Trustees, and only under the limited circumstances specified in rule 23c–3(b)(3)(i). The Funds will not condition a repurchase offer upon tender of any minimum amount of shares. In addition, each Fund will comply with the pro ration and other allocation requirements of rule 23c–3(b)(5) if common shareholders tender more than the repurchase offer amount. Further, each Fund will permit tenders to be withdrawn or modified at any time until the repurchase request deadline, but will not permit tenders to be withdrawn or modified thereafter.

9. From the time a Fund sends its notification to shareholders of the repurchase offer until the repurchase pricing date, a percentage of such Fund's assets equal to at least 100% of the repurchase offer amount will consist of: (a) Assets that can be sold or disposed of in the ordinary course of business at approximately the price at which such Fund has valued such investment within a period equal to the period between the repurchase request deadline and the repurchase payment deadline; or (b) assets that mature by the next repurchase payment deadline. In the event the assets of a Fund fail to comply with this requirement, the Board will cause such Fund to take such action as it deems appropriate to ensure compliance.

10. In compliance with the asset coverage requirements of section 18 of the Act, any senior security issued by, or other indebtedness of, a Fund will either mature by the next repurchase pricing date or provide for such Fund's ability to call, repay or redeem such senior security or other indebtedness by the next repurchase pricing date, either in whole or in part, without penalty or premium, as necessary to permit that Fund to complete the repurchase offer in such amounts determined by its Board.

11. The Board of each Fund will adopt written procedures to ensure that such Fund's portfolio assets are sufficiently liquid so that it can comply with its fundamental policy on repurchases and the liquidity requirements of rule 23c–3(b)(10)(i). The Board of each Fund will review the overall composition of the portfolio and make and approve such changes to the procedures as it deems necessary.

Applicants' Legal Analysis

1. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of the Act or rule thereunder, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

2. Section 23(c) of the Act provides in relevant part that no registered closed-end investment company shall purchase any securities of any class of which it is the issuer except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under such other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

3. Rule 23c–3 under the Act permits a registered closed-end investment company to make repurchase offers for its common stock at net asset value at periodic intervals pursuant to a fundamental policy of the investment company. ''Periodic interval'' is defined in rule 23c–3(a)(1) as an interval of three, six, or twelve months. Rule 23c–3(b)(4) requires that notification of each repurchase offer be sent to shareholders no less than 21 calendar days and no more than 42 calendar days before the repurchase request deadline.

4. Applicants request an order pursuant to sections 6(c) and 23(c) of the Act exempting them from rule 23c–3(a)(1) to the extent necessary to permit the Funds to make monthly repurchase offers. Applicants also request an exemption from the notice provisions of rule 23c–3(b)(4) to the extent necessary to permit each Fund to send notification of an upcoming repurchase offer to shareholders at least seven days but no more than fourteen calendar days in advance of the repurchase request deadline.

5. Applicants contend that monthly repurchase offers are in the public interest and in the common shareholders' interests and consistent with the policies underlying rule 23c–3. Applicants assert that monthly repurchase offers will provide investors with more liquidity than quarterly repurchase offers. Applicants assert that shareholders will be better able to manage their investments and plan transactions, because if they decide to forego a repurchase offer, they will only need to wait one month for the next offer. Applicants also contend that the portfolio of each Fund will be managed to provide ample liquidity for monthly repurchase offers.

6. Applicants propose to send notification to shareholders at least seven days, but no more than fourteen calendar days, in advance of a repurchase request deadline. Applicants assert that, because the Fund (and any Future Fund) currently intends to make payment on the fifth business day or seventh calendar day (whichever period is shorter) following the repurchase pricing date, the entire procedure will be completed before the next notification is sent out to shareholders, thus avoiding any overlap. Applicants believe that these procedures will eliminate any possibility of investor confusion. Applicants also state that monthly repurchase offers will be a fundamental feature of the Funds, and their prospectuses will provide a clear explanation of the repurchase program.

7. Applicants submit that for the reasons given above the requested relief is appropriate in the public interest and is consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the following conditions:

1. The Fund (and any Future Fund relying on this relief) will make a repurchase offer pursuant to rule 23c–3(b) for a repurchase offer amount of not less than 5% in any one-month period. In addition, the repurchase offer amount for the then-current monthly period, plus the repurchase offer amounts for the two monthly periods immediately preceding the then-current monthly period, will not exceed 25% of the Fund's (or Future Fund's, as applicable) outstanding common shares. The Fund (and any Future Fund relying on this relief) may repurchase additional tendered shares pursuant to rule 23c–3(b)(5) only to the extent the percentage of additional shares so repurchased does not exceed 2% in any three-month period.

2. Payment for repurchased shares will occur at least five business days before notification of the next repurchase offer is sent to shareholders of the Fund (or Future Fund relying on this relief).

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–15297 Filed 7–14–20; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Docket No. SBA–2020–0041]

Community Advantage Pilot Program Temporary Changes—Community Advantage Recovery Loans

AGENCY: U.S. Small Business Administration.

ACTION: Temporary changes to Community Advantage Pilot Program and request for comments.

SUMMARY: The Community Advantage (CA) Pilot Program is a pilot program to increase SBA-guaranteed loans to small businesses in underserved areas. In response to the Coronavirus Disease 2019 (COVID–19) pandemic, SBA has developed a new, temporary CA loan product titled ''Community Advantage Recovery Loans'' (CA Recovery Loans) for eligible CA Lenders to provide technical and financial assistance to assist small businesses located in underserved areas with retooling their business models for the COVID–19 environment and building financial resiliency against potential future disruptions. SBA is issuing this document to provide the specific requirements for CA Recovery Loans.

DATES: The changes to the CA Pilot program identified in this document take effect July 15, 2020. CA Recovery Loans can be approved through September 27, 2020 and must be fully disbursed no later than October 1, 2020.

Comment Date: Comments must be received on or before August 14, 2020.

ADDRESSES: You may submit comments, identified by SBA docket number SBA-2020–0041 through the Federal eRulemaking Portal: *https://www.regulations.gov/.* Follow the instructions for submitting comments.

SBA will post all comments on *https://www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *https://www.regulations.gov,* please send an email to *communityadvantage@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination as to whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Daniel Upham, Chief, Microenterprise Development Division, or Rosemarie Drake, Chief, 7(a) Loan Division, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416, (202) 205–7001, *daniel.upham@sba.gov* or (202) 619–1674, *rosemarie.drake@sba.govmailto:*.

SUPPLEMENTARY INFORMATION:

1. Background

On March 13, 2020, President Trump declared the ongoing COVID–19 pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, territories, and the District of Columbia. With the COVID–19 emergency, many small businesses nationwide are experiencing economic hardship as a direct result of the Federal, State, and local public health measures that are being taken to minimize the public's exposure to the virus. These measures, some of which are government-mandated, have been implemented nationwide and include the closures of restaurants, bars, and gyms. In addition, based on the advice of public health officials, other measures, such as keeping a safe distance from others or even stay-at-home orders, have been implemented, resulting in a dramatic decrease in economic activity as the public avoids malls, retail stores, and other businesses.

On March 27, 2020, the President signed the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act or the Act) (Pub. L. 116–136) to provide emergency assistance and health care response for individuals, families, and businesses affected by the coronavirus pandemic. The Small Business Administration (SBA) received funding and authority through the Act to modify existing loan programs to assist small businesses nationwide adversely impacted by the COVID–19 emergency.

As part of its efforts to increase the number of SBA-guaranteed 7(a) loans made to small businesses in underserved markets, on February 18, 2011, SBA issued a notice and request for comments introducing the CA Pilot Program (76 FR 9626). That notice provided an overview of the CA Pilot Program requirements and, pursuant to the authority provided to SBA under 13 CFR 120.3 to suspend, modify or waive certain regulations in establishing and testing pilot loan initiatives, SBA modified or waived as appropriate certain regulations which otherwise apply to 7(a) loans for the CA Pilot Program.

Subsequent notices have made changes to the CA Pilot Program to improve the program experience for participants, improve their ability to deliver capital to underserved markets, and appropriately manage risk to the Agency. These notices were issued on the following dates: September 12, 2011 (76 FR 56262), February 8, 2012 (77 FR 6619), November 9, 2012 (77 FR 67433), December 28, 2015 (80 FR 80872), September 12, 2018 (83 FR 46237), and March 2, 2020 (85 FR 12369).

SBA is issuing this document to establish a new, temporary CA loan product in response to the COVID–19 emergency. CA Recovery Loans will be available to small businesses located in underserved markets from certain existing CA Lenders through September 27, 2020. CA policies and regulatory waivers apply to CA Recovery Loans, except as outlined in this Notice. The policies and regulatory waivers described below apply only to CA Recovery Loans. Other CA loans continue to be governed by the existing CA Loan Program Requirements.[1]

2. Comments

Although the changes are effective July 15, 2020, comments are solicited from interested members of the public. Comments must be submitted on or before the deadline for comments listed in the **DATES** section. SBA will consider these comments and the need for making any revisions as a result of these comments.

3. Community Advantage Recovery Loans

a. Overview

The CARES Act was enacted to provide immediate assistance to individuals, families, and businesses affected by the COVID–19 emergency. Under section 1112 of the CARES Act, SBA will provide debt relief to borrowers in the 7(a) (including the CA Pilot Program), 504, and Microloan Programs. As discussed more fully below, through the CA Recovery Loans, SBA intends to leverage this authority to provide debt relief to borrowers with technical and financial assistance to maximize the assistance available to borrowers in underserved markets.

SBA's authority under section 1112, as further described below, is in effect for loans made through September 27, 2020, which will be the final day for the approval of CA Recovery Loans.

[1] ''CA Loan Program Requirements'' means Loan Program Requirements as defined in 13 CFR 120.10, and the requirements contained in the **Federal Register** notices governing the pilot and the Community Advantage Participant Guide, as amended from time to time.

b. Eligible Lenders

In light of the potential risks associated with CA Recovery Loans and the short period of time during which CA Recovery Loans may be made, only certain lenders that are already participating in the CA Pilot Program will be eligible to make CA Recovery Loans. Several key metrics have been used to identify eligible lenders, including CA loan volume, portfolio performance metrics and most recent lender review results. Within 5 business days of the publication of this document, SBA will notify existing CA Lenders that are eligible to make CA Recovery Loans (referred to in this Notice as ''CA Recovery Lenders'') and provide instructions on how to opt in if they choose to participate. Once a CA Recovery Lender has opted in, it will be able to enter loans in ETRAN as a CA Recovery Loan. Other CA Lenders may refer and/or package loans for CA Recovery Lenders for a fee, as described in paragraph e. below.

c. CA Recovery Loan Terms and Conditions

All CA Recovery Loans must be made to small businesses located in underserved markets, as defined in the CA Participant Guide available on SBA's website at *https://www.sba.gov/sites/default/files/2020-06/CA%20Guide%20Version%206%20FINAL%20508%2006-01-20.pdf,* and must be accompanied by technical assistance (TA) provided to the borrower by or on behalf of the CA Recovery Lender. The TA is for the purpose of assisting the borrower to build financial resiliency against future business disruptions and must be for a minimum of 15 hours. The TA may begin 30 days before loan approval and must be completed during the first six months of the CA Recovery Loan term. The cost of the technical assistance is to be paid out of the extraordinary servicing fee described in paragraph d. below. No other fees may be charged by the lender on CA Recovery Loans, except for necessary out-of-pocket expenses, such as filing or recording fees, under 13 CFR 120.221(c).

All CA Recovery Loans must be approved by September 27, 2020 and must be fully disbursed no later than October 1, 2020. The minimum loan term for a CA Recovery Loan is five years.

All other loan terms and conditions for CA Recovery Loans are the same as the terms and conditions for other CA loans, as set forth in the CA Loan Program Requirements. CA Recovery Lenders are reminded that they must maintain adequate loan loss reserves to cover potential losses arising from defaulted CA loans, including any CA Recovery Loans.[2]

d. Allowable Extraordinary Servicing Fee for CA Recovery Loans and Technical Assistance Requirement

For CA Recovery Loans only, SBA is modifying the requirements of 13 CFR 120.221(b) to permit a CA Recovery Lender to charge up to $2,500 or nine percent of the amount of the CA Recovery Loan, whichever is greater, as an extraordinary servicing fee to cover the cost of the required technical assistance provided by or on behalf of the CA Recovery Lender to each CA Recovery Loan borrower. Such TA is to be tailored to the needs of the particular borrower and may include retooling the borrower's business model for a COVID–19 environment, shifting to an online presence, building cash reserves, and expense reduction strategies. As indicated above, the CA Recovery Lender must ensure that each CA Recovery Loan borrower receives, at a minimum, 15 hours of TA, which may begin 30 days prior to loan approval and must be completed during the first six months of the CA Recovery Loan term.

While SBA will not require the CA Recovery Lender to obtain SBA's prior written approval of these extraordinary servicing fees as is normally required under 13 CFR 120.221(b), the CA Recovery Lender must document all TA provided to a CA Recovery Loan borrower in the loan file. SBA will review this documentation when conducting lender oversight activities or, in the event of default, at time of guaranty purchase. SBA may deny liability on the guaranty if the TA is not provided or the CA Recovery Lender is unable to document that the TA was provided. In addition, SBA may seek repayment of the extraordinary servicing fee from the CA Recovery Lender if the TA was not provided or the CA Recovery Lender is unable to document that the TA was provided. No additional service and packaging fees will be permitted to be charged under section 120.221(a) on CA Recovery Loans.

An extraordinary servicing fee of up to $2,500 or nine percent of the CA Recovery Loan amount, whichever is greater, is in recognition that CA Recovery Loans will require more engagement and resources on the part of the lender than other loans,[3] including other CA loans. This extraordinary servicing fee would ordinarily be the responsibility of the borrower but will be paid by SBA under section 1112 of the CARES Act instead of the borrower (see paragraph f. below). In accordance with the requirements of section 1112, SBA will only pay the CA Recovery Lender an extraordinary servicing fee on CA Recovery Loans that are fully disbursed and are in regular servicing. After a loan is fully disbursed and reported to the Fiscal Transfer Agent on the 1502 report, SBA will pay the extraordinary servicing fee to the CA Recovery Lender. SBA will provide additional guidance with details on the method of payment.

e. CA Recovery Lenders and Use of Agents

CA Recovery Lenders may enter into agreements with other mission-oriented organizations (including CA Lenders that are not eligible to make CA Recovery Loans), as well as depository and non-depository financial institutions, to act as loan referral agents and/or packagers, but may not use agents for other services (such as underwriting) on CA Recovery Loans. For CA Loan Program Requirements concerning the use of referral agents and packagers, see the CA Participant Guide, which can be found at *https://www.sba.gov/sites/default/files/2020-06/CA%20Guide%20Version%206%20FINAL%20508%2006-01-20.pdf.*

For CA Recovery Loans, SBA is modifying 13 CFR 103.5 to clarify the fees that a CA Recovery Lender may pay to an agent in connection with assistance provided on a CA Recovery Loan. As modified, an agent will be permitted to receive reasonable compensation from a CA Recovery Lender for referring and/or packaging a CA Recovery Loan application to the CA Recovery Lender, and the compensation may be contingent upon funding of the CA Recovery Loan. Referral and/or packaging fees paid by a CA Recovery Lender in connection with a CA Recovery Loan will not be permitted to exceed $3,000 for all agent services provided in connection with the CA Recovery Loan. Based on the fact that only referral and/or packaging services will be provided to a CA Recovery Lender who will perform its own

[2] As set forth in section VI of the CA Participant Guide (ver. 6.0, effective June 15, 2020), the Loan Loss Reserve Account must equal no less than 5% of the outstanding balance of the unguaranteed portion of the CA Lender's CA loan portfolio and an additional 5% reserve amount is required to be maintained on the guaranteed portion of each CA loan that is sold into the secondary market.

[3] Under the Paycheck Protection Program (PPP) authorized by section 1102 of the CARES Act, lenders are paid a 5% processing fee on PPP loans of up to $350,000, with no technical assistance required on the part of the lender.

underwriting, SBA has determined that a ceiling of $3,000 is reasonable for such services. The compensation paid for referral and/or packaging services must be paid by the CA Recovery Lender and may not be charged to the borrower. Any payment for referral and/or packaging must be reported by the CA Recovery Lender on SBA Form 159.

f. Application of CARES Act Sec. 1112 Payments

Under Section 1112 of the CARES Act, SBA will pay the principal, interest, and any ''associated fees'' that Borrowers owe on a covered loan in a regular servicing status to CA Lenders for a 6-month period. SBA issued two procedural notices to implement Section 1112: SBA Procedural Notice 5000–20020, effective April 16, 2020, and SBA Procedural Notice 5000–20023, effective April 29, 2020. In SBA Procedural Notice 5000–20020, SBA defined ''associated fees'' to include the extraordinary servicing fee authorized by 13 CFR 120.221(b). For CA Recovery Loans, SBA ''associated fees'' will include the extraordinary servicing fee paid to the CA Recovery Lender for technical assistance as described above in paragraph d. SBA believes that the technical assistance provided by or on behalf of the CA Recovery Lender to the borrower on a CA Recovery Loan, which must be completed by the end of the first six months of the loan term, is similar to the services for which an extraordinary servicing fee is paid on other 7(a) loans under section 1112 of the CARES Act. All other provisions relating to Section 1112 payments apply to CA Recovery Loans as set forth in SBA Procedural Notices 5000–20020 and 5000–20023, and any applicable amendments or future notices.

4. General Information

The changes in this document are limited to CA Recovery Loans made under the CA Pilot Program only; they do not apply to other CA loans. Except as provided in this document, all other CA Loan Program Requirements, including regulatory waivers or modifications related to the CA Pilot Program, also apply to CA Recovery Loans. SBA may provide additional guidance, through SBA notices, which may also be published on SBA's website at *http://www.sba.gov/category/lender-navigation/forms-notices-sops/notices.* Questions regarding the CA Pilot Program may be directed to the Lender Relations Specialist in the local SBA district office. The local SBA district office may be found at *http://www.sba.gov/about-offices-list/2.*

Authority: 15 U.S.C. 636(a)(25); Coronavirus Aid, Relief, and Economic Security Act, Publ. L. 116–136, and 13 CFR 120.3.

Dated: July 6, 2020.

Jovita Carranza,

Administrator.

[FR Doc. 2020–14852 Filed 7–14–20; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 11154]

60-Day Notice of Proposed Information Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *September 14, 2020.*

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2020–0030'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: watkinspk@state.gov.*

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Pamela Watkins, Department of State, Office of Directives Management, who may be reached at *watkinspk@state.gov* or 202–485–2159.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery
- *OMB Control Number:* 1405–0193
- *Type of Request:* Extension of a Currently Approved Collection
- *Originating Office:* Office of Directives Management, A/GIS/DIR
- *Form Number:* Various public surveys
- *Respondents:* Individuals responding to Department of State customer service evaluation requests
- *Estimated Number of Respondents:* 1,000,000
- *Estimated Number of Responses:* 1,000,000
- *Average Time per Response:* 3.5 minutes
- *Total Estimated Burden Time:* 58,333 annual hours
- *Frequency:* Once per request
- *Obligation to Respond:* Voluntary

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The information collection activity will garner qualitative customer feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. This qualitative feedback will provide insights into customer perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be used for quantitative

information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Methodology

Respondents will fill out a brief customer survey after completing their interaction with a Department Program Office or Embassy. Surveys are designed to gather feedback on the customer's experiences.

Zachary Parker,

Director.

[FR Doc. 2020–15286 Filed 7–14–20; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF STATE

[Public Notice 11150]

60-Day Notice of Proposed Information Collection: Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)

ACTION: Notice; request for comment.

SUMMARY: The Department of State as part of its continuing effort to reduce paperwork and respondent burden, is announcing an opportunity for public comment on a new proposed collection of information by the Agency. 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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on new collection proposed by the Agency.

DATES: The Department will accept comments from the public up to September 14, 2020.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2020–0029'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: watkinspk@state.gov.*

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Pamela Watkins, who may be reached on 202–485–2159 or at *watkinspk@state.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, GSA is publishing notice of the proposed collection of information set forth in this document.

Whether seeking a loan, Social Security benefits, veteran's benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector.

A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: Conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. The Department of State will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on performance.gov to help build transparency and accountability of Federal programs to the customers they serve.

Method of Collection

The Department of State will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. The Department of State may also utilize observational techniques to collect this information.

Data:

Form Number(s): None.

Type of Review: New.

B. Annual Reporting Burden

Affected Public: Collections will be targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future. For the purposes of this request, ''customers'' are individuals, businesses, and organizations that interact with a Federal Government agency or program, either directly or via a Federal contractor. This could include individuals or households; businesses or other for-profit organizations; not-for-profit institutions; State, local or tribal

governments; Federal Government; and Universities.

- *Estimated Number of Respondents:* 2,001,550.
- *Estimated Time per Response:* Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 1.5 hours to participate in an interview.
- *Estimated Total Annual Burden Hours:* 101,125.
- *Estimated Total Annual Cost to Public:* $0.

C. Public Comments

The Department of State invites 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 will have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Zachary Parker,

Director.

[FR Doc. 2020–15285 Filed 7–14–20; 8:45 am]

BILLING CODE 4710–24–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Product Exclusion Amendments: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of product exclusion amendments.

SUMMARY: In September 2018, the U.S. Trade Representative imposed additional duties on goods of China with an annual trade value of approximately $200 billion as part of the action in the Section 301 investigation of China's acts, policies, and practices related to technology transfer, intellectual property, and innovation. The U.S. Trade Representative initiated a product exclusion process in June 2019, and interested persons have submitted requests for the exclusion of specific products. This notice announces the U.S. Trade Representative's determination to make technical amendments to previously announced exclusions.

DATES: The amendments announced in this notice are retroactive to the date of publication of the original exclusions.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Associate General Counsel Philip Butler, Assistant General Counsel Megan Grimball, or Director of Industrial Goods Justin Hoffmann at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusions identified in the Annex to this notice, contact *traderemedy@cbp.dhs.gov*.

SUPPLEMENTARY INFORMATION:

A. Background

For background on the proceedings in this investigation, please see prior notices including 82 FR 40213 (August 24, 2017), 83 FR 14906 (April 6, 2018), 83 FR 28710 (June 20, 2018), 83 FR 33608 (July 17, 2018), 83 FR 38760 (August 7, 2018), 83 FR 47974 (September 21, 2018), 83 FR 49153 (September 28, 2018), 83 FR 65198 (December 19, 2018), 84 FR 7966 (March 5, 2019), 84 FR 20459 (May 9, 2019), 84 FR 29576 (June 24, 2019), 84 FR 38717 (August 7, 2019), 84 FR 46212 (September 3, 2019), 84 FR 49591 (September 20, 2019), 84 FR 57803 (October 28, 2019), 84 FR 61674 (November 13, 2019), 84 FR 65882 (November 29, 2019), 84 FR 69012 (December 17, 2019), 85 FR 549 (January 6, 2020), 85 FR 6674 (February 5, 2020), 85 FR 9921 (February 20, 2020), 85 FR 15015 (March 16, 2020), 85 FR 17158 (March 26, 2020), 85 FR 23122 (April 24, 2020), 85 FR 27489 (May 8, 2020), 85 FR 32094 (May 28, 2020), and 85 FR 38000 (June 24, 2020).

Effective September 24, 2018, the U.S. Trade Representative imposed additional 10 percent *ad valorem* duties on goods of China classified in 5,757 full and partial subheadings of the Harmonized Tariff Schedule of the United States (HTSUS), with an approximate annual trade value of $200 billion. *See* 83 FR 47974, as modified by 83 FR 49153. In May 2019, the U.S. Trade Representative increased the additional duty to 25 percent. *See* 84 FR 20459. On June 24, 2019, the U.S. Trade Representative established a process by which stakeholders could request exclusion of particular products classified within an eight-digit HTSUS subheading covered by the $200 billion action from the additional duties. *See* 84 FR 29576 (June 24 notice).

Under the June 24 notice, requests for exclusion had to identify the product subject to the request in terms of the physical characteristics that distinguish the product from other products within the relevant eight-digit HTSUS subheading covered by the $200 billion action. Requestors also had to provide the ten-digit HTSUS subheading most applicable to the particular product requested for exclusion, and could submit information on the ability of U.S. Customs and Border Protection to administer the requested exclusion. Requestors were asked to provide the quantity and value of the Chinese-origin product that the requestor purchased in the last three years. With regard to the rationale for the requested exclusion, requests had to address the following factors:

- Whether the particular product is available only from China and specifically whether the particular product and/or a comparable product is available from sources in the United States and/or third countries.
- Whether the imposition of additional duties on the particular product would cause severe economic harm to the requestor or other U.S. interests.
- Whether the particular product is strategically important or related to ''Made in China 2025'' or other Chinese industrial programs.

The June 24 notice stated that the U.S. Trade Representative would take into account whether an exclusion would undermine the objective of the Section 301 investigation.

The June 24 notice required submission of requests for exclusion from the $200 billion action no later than September 30, 2019, and noted that the U.S. Trade Representative periodically would announce decisions. In August 2019, the U.S. Trade Representative granted an initial set of exclusion requests. *See* 84 FR 38717. The U.S. Trade Representative granted additional exclusions in September, October, November and December 2019, and in January, February, March, April, May and June 2020. *See* 84 FR 49591; 84 FR 57803; 84 FR 61674; 84 FR 65882; 84 FR 69012; 85 FR 549; 85 FR 6674; 85 FR 9921; 85 FR 15015; 85 FR 17158; 85 FR 23122; 85 FR 27489; 85 FR 32094; and 85 FR 38000. The Office of the United States Trade Representative regularly updates the status of each

pending request on the Exclusions Portal at *https://exclusions.ustr.gov/s/docket?docketNumber=USTR-2019-0005*.

B. Technical Amendments to Exclusions

The Annex contains 14 technical amendments to U.S. notes 20(ll)(24) and (25); U.S. notes 20(vv)(71) and (116); U.S. notes 20(xx)(20), (43), and (44); U.S. notes 20(yy)(75), (113), (116), (117), (118), and (138); and U.S. note 20(aaa)(47) to subchapter III of chapter 99 of the HTSUS, as set out in the Annexes of the notices published at 84 FR 57803 (October 28, 2019), 85 FR 17158 (Match 26, 2020), 85 FR 23122 (April 24, 2020), 85 FR 27489 (May 8, 2020), and 85 FR 32094 (May 28, 2020). The Annex also makes three additional amendments to accommodate conforming changes to the HTSUS: U.S. note 20(qq)(35), U.S. note 20(vv)(79), and U.S. note 20(aaa)(49) to subchapter III of chapter 99 of the HTSUS, published at 85 FR 6674 (February 5, 2020), 85 FR 17158 (Match 26, 2020), and 85 FR 32094 (May 28, 2020).

As stated in the September 20, 2019 notice, the exclusions apply from September 24, 2018 to August 7, 2020. U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

The U.S. Trade Representative will continue to issue determinations on pending requests on a periodic basis.

Annex

Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on September 24, 2018, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

1. U.S. note 20(ll)(24) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''valued not over $0.10 per kg'' and inserting ''valued not over $0.05 per piece'' in lieu thereof.

2. U.S. note 20(ll)(25) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''valued not over $0.10 per kg'' and inserting ''valued not over $0.07 per piece'' in lieu thereof.

3. U.S. note 20(vv)(71) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''with adhesive on one side, in rectangular sheets having rounded corners, each measuring 55 mm by 120 mm but no more than 212 mm by 278 mm and at least 0.51 mm but no more than 0.55 mm in thickness'' and inserting ''transparent, cut, and treated, with adhesive on one side, in rectangular sheets, each weighing at least 6 g but not more than 77 g, each measuring not less than 2.8 cm but not more than 28 cm in height, not less than 1.9 cm but not more than 21 cm in width, and not more than 0.1 cm in thickness'' in lieu thereof.

4. U.S. note 20(vv)(116) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''incorporating permanent split capacitors,'' and inserting ''whether or not incorporating permanent split capacitors,'' in lieu thereof.

5. U.S. note 20(xx)(20) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''without hydration systems,''.

6. U.S. note 20(xx)(43) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''each measuring no less than 328 mm by 127 mm by 107 mm and no more than 352 mm by 209 mm by 162 mm'' and inserting ''each measuring no less than 323 mm by 122 mm by 102 mm and no more than 357 mm by 214 mm by 167 mm'' in lieu thereof.

7. U.S. note 20(xx)(44) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''each measuring not less than 350 mm by 127 mm by 107 mm and not more than 350 mm by 168 mm by 140 mm, of an output of 115 W to 280 W, and weighing at least 1.85 kg and no more than 2.08 kg'' and inserting ''each measuring not less than 345 mm by 122 mm by 102 mm and not more than 355 mm by 173 mm by 145 mm, of an output of 100 W to 285 W, and weighing at least 1.80 kg but no more than 2.72 kg'' in lieu thereof.

8. U.S. note 20(yy)(75) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''with 89 mm pump and 11 gauge steel forks'' and inserting ''with a pump measuring between 89 mm and 105 mm and steel forks with a Gauge Range between 9–12'' in lieu thereof.

9. U.S. note 20(yy)(113) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''suitable for use in automatic transmission systems for passenger motor vehicles (described in statistical reporting number 8708.99.6890)'' and inserting ''(described in statistical reporting number 8708.40.7570)'' in lieu thereof.

10. U.S. note 20(yy)(116) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''suitable for use in automatic transmission systems for passenger motor vehicles (described in statistical reporting number 8708.99.6890)'' and inserting ''(described in statistical reporting number 8708.40.7570)'' in lieu thereof.

11. U.S. note 20(yy)(117) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''suitable for use in automatic transmission systems for passenger motor vehicles (described in statistical reporting number 8708.99.6890)'' and inserting ''(described in statistical reporting number 8708.40.7570)'' in lieu thereof.

12. U.S. note 20(yy)(118) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''suitable for use in automatic transmission systems for passenger motor vehicles (described in statistical reporting number 8708.99.6890)'' and inserting ''(described in statistical reporting number 8708.40.7570)'' in lieu thereof.

13. U.S. note 20(yy)(138) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''not more than 25.4 cm in height'' and inserting ''not more than 45 cm in height'' in lieu thereof.

14. U.S. note 20(aaa)(47) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''for assembly in cuplock configurations'' and inserting ''for assembly in ringlock or cuplock configurations'' in lieu thereof.

15. U.S. note 20(qq)(35) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''(described in statistical reporting number 4823.90.8600)'' and inserting ''(described in statistical reporting number 4823.90.8600 prior to July 1, 2020; described in statistical reporting number 4823.90.8680 effective July 1, 2020)'' in lieu thereof.

16. U.S. note 20 (vv)(79) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''(described in statistical reporting number 7310.10.0010)'' and inserting ''(described in statistical reporting number 7310.10.0010) prior to July 1, 2020; described in statistical reporting number 7310.10.0015 effective July 1, 2020)'' in lieu thereof.

17. U.S. note 20(aaa)(49) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''(described in statistical reporting number 7310.10.0010)'' and inserting ''(described in statistical reporting number 7310.10.0010 prior to July 1, 2020; described in statistical reporting number 7310.10.0015 effective July 1, 2020)'' in lieu thereof.

Joseph Barloon,

General Counsel, Office of the U.S. Trade Representative.

[FR Doc. 2020–15288 Filed 7–14–20; 8:45 am]

BILLING CODE 3290–F0–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Product Exclusion Amendment: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: Effective July 6, 2018, the U.S. Trade Representative imposed additional duties on goods of China with an annual trade value of approximately $34 billion as part of the action in the Section 301 investigation of China's acts, policies, and practices related to technology transfer, intellectual property, and innovation. The U.S. Trade Representative's determination included a decision to establish a product exclusion process, which was initiated in July 2018. Stakeholders submitted requests for the exclusion of specific products and the U.S. Trade Representative has issued determinations to grant exclusion requests. This notice announces the U.S. Trade Representative's determination to make a technical amendment to a previously granted exclusion.

DATES: This technical amendment is retroactive to the date of publication of the original exclusion and does not extend the period for the original exclusion. U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Associate General Counsel Philip Butler or Director of Industrial Goods Justin Hoffmann at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusions identified in the Annex to this notice, contact *traderemedy@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

For background on the proceedings in this investigation, please see prior notices including 82 FR 40213 (August 24, 2017), 83 FR 14906 (April 6, 2018), 83 FR 28710 (June 20, 2018), 83 FR 33608 (July 17, 2018), 83 FR 38760 (August 7, 2018), 83 FR 40823 (August 16, 2018), 83 FR 47974 (September 21, 2018), 83 FR 65198 (December 19, 2018), 83 FR 67463 (December 28, 2018), 84 FR 7966 (March 5, 2019), 84 FR 11152 (March 25, 2019), 84 FR 16310 (April 18, 2019), 84 FR 21389 (May 14, 2019), 84 FR 25895 (June 4, 2019), 84 FR 32821 (July 9, 2019), 84 FR 49564 (September 20, 2019), 84 FR 52567 (October 2, 2019), 84 FR 69016 (December 17, 2019), 85 FR 7816 (February 11, 2020), 85 FR 28692 (May 13, 2020), and 85 FR 35158 (June 8, 2020).

Effective July 6, 2018, the U.S. Trade Representative imposed additional 25 percent duties on goods of China classified in 818 eight-digit subheadings of the Harmonized Tariff Schedule of the United States (HTSUS), with an approximate annual trade value of $34 billion. *See* 83 FR 28710. The U.S. Trade Representative's determination included a decision to establish a process by which U.S. stakeholders could request exclusion of particular products classified within an eight-digit HTSUS subheading covered by the $34 billion action from the additional duties. The U.S. Trade Representative issued a notice setting out the process for the product exclusions and opened a public docket. *See* 83 FR 32181 (the July 11 notice).

Under the July 11 notice, requests for exclusion had to identify the product subject to the request in terms of the physical characteristics that distinguish the product from other products within the relevant eight-digit subheading covered by the $34 billion action. Requestors also had to provide the ten-digit subheading of the HTSUS most applicable to the particular product requested for exclusion, and could submit information on the ability of U.S. Customs and Border Protection to administer the requested exclusion. Requestors were asked to provide the quantity and value of the Chinese-origin product that the requestor purchased in the last three years. With regard to the rationale for the requested exclusion, requests had to address the following factors:

- Whether the particular product is available only from China and, specifically, whether the particular product and/or a comparable product is available from sources in the United States and/or third countries.
- Whether the imposition of additional duties on the particular product would cause severe economic harm to the requestor or other U.S. interests.
- Whether the particular product is strategically important or related to ''Made in China 2025'' or other Chinese industrial programs.

The July 11 notice stated that the U.S. Trade Representative would take into account whether an exclusion would undermine the objective of the Section 301 investigation.

The July 11 notice required submission of requests for exclusion from the $34 billion action no later than October 9, 2018, and noted that the U.S. Trade Representative periodically would announce decisions. In December 2018, the U.S. Trade Representative granted an initial set of exclusion requests. *See* 83 FR 67463. The U.S. Trade Representative announced additional determinations in March, April, May, June, July, September, October, and December 2019; and February, May, and June 2020. *See* 84 FR 11152; 84 FR 16310; 84 FR 21389; 84 FR 25895; 84 FR 32821; 84 FR 49564; 84 FR 52567; 84 FR 69016; 85 FR 7816; 85 FR 28692; and 85 FR 35158.

B. Technical Amendments to Exclusions

The Annex to this notice makes one technical amendment to U.S. note 20(x)(97) to subchapter III of chapter 99 of the HTSUS, as set out in the Annex of the notice published at 85 FR 7816 (February 11, 2020).

The U.S. Trade Representative will continue to issue determinations on a periodic basis as needed.

Annex

Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on July 6, 2018, and before October 2, 2020:

1. U.S. note 20(x)(97) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States, is modified by deleting ''Multi-phase AC motors of an output of at least 5.8 kW but not exceeding 14.92 kW, each assembled with planetary gears and a gearbox (described in statistical reporting number 8501.52.4000).''

Joseph Barloon,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2020–15289 Filed 7–14–20; 8:45 am]

BILLING CODE 3290–F0–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–48]

Petition for Exemption; Summary of Petition Received; Breeze Airways

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 4, 2020.

ADDRESSES: Send comments identified by docket number FAA–2020–0479 using any of the following methods:

- *Federal eRulemaking 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, 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 20590–0001, 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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 the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michelle Ross, (202) 267–9836, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 9, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0479.
Petitioner: Breeze Airways.
Section(s) of 14 CFR Affected: § 121.652(a) and (c).
Description of Relief Sought: The petitioner requests relief to allow their pilots in command (PIC) conducting operations under part 121 to perform an instrument approach procedure to the weather minima prescribed by Exemption No. 5549 during the first 100 hours of service as PIC, using an alternative approved means.

[FR Doc. 2020–15232 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–43]

Petition for Exemption; Summary of Petition Received; William Bryant

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before July 20, 2020.

ADDRESSES: Send comments identified by docket number FAA–2020–0381 using any of the following methods:

- *Federal eRulemaking 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, 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 20590–0001, 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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 the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Brenda Robeson, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 9, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0381.
Petitioner: William Bryant.
Section(s) of 14 CFR Affected: § 61.58.
Description of Relief Sought: Mr. William Bryant is petitioning for relief from the requirements of § 61.58 (Pilot-in-command (PIC) proficiency check). Section 61.58 requires that to serve as pilot-in-command of an aircraft that is type certificated for more than one required pilot flight crewmember or is turbojet-powered, a person must, within the preceding 12 calendar months, complete a PIC proficiency check in an

aircraft that is type certificated for more than one required pilot flight crewmember or is turbojet-powered. In the petition, Mr. Bryant stated that his next PIC proficiency check is due in March 2021. The exemption requested would extend the due date for Mr. Bryant's PIC proficiency check for 90 days beyond the current March 2021 expiration.

[FR Doc. 2020–15231 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–18]

Petition for Exemption; Summary of Petition Received; Bridger Aviation Services, LLC

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 4, 2020.

ADDRESSES: Send comments identified by docket number FAA–2019–1033 using any of the following methods:

- *Federal eRulemaking 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, 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 20590–0001, 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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 the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 9, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2019–1033.

Petitioner: Bridger Aviation Services, LLC.

Section(s) of 14 CFR Affected: Part 21, Subpart H; 14 CFR 91.105(a)(2); 91.109; 91.405; 91.407; 91.409; & 91.417.

Description of Relief Sought: The proposed exemption, if granted, would allow Bridger Aviation Services, LLC to operate the Latitude FVR–90 unmanned aircraft system (UAS), with a maximum takeoff weight of 117 pounds, within the national airspace system in support of the Department of Interior UAS contract and other customers. The scope of these operations include: Surveys, cattle counts, burned area recovery surveys, transmission line surveys, pipeline surveys, railroad surveys, disaster relief efforts, wildfire management, pilot training operations, ecology surveys, and any other similar surveys. The petitioner is proposing to conduct operations: Beyond visual line of sight; below 14,000 feet; and, at maximum airspeed of 70 knots.

[FR Doc. 2020–15230 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–32]

Petition for Exemption; Summary of Petition Received; Zipline International, Inc.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 4, 2020.

ADDRESSES: Send comments identified by docket number FAA–2020–0499 using any of the following methods:

- *Federal eRulemaking 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, 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 20590–0001, 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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 the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267–7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 9, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0499.

Petitioner: Zipline International, Inc.

Sections of 14 CFR Affected: §§ 61.3(a); 61.133; 91.7(a); 91.119(b)–(c); 91.121; 91.151(a); 135.25(a); 135.63(c)–(d); 135.149(a); 135.161(a); 135.203(a); 135.209(a); 135.243(b)(1)–(3); 135.267; 135.337(b)(1); 135.338(b)(1); 135.339(e)(3) and (4); and 135.340(e)(3) and (4).

Description of Relief Sought: Zipline International, Inc. petitions for exemptions to conduct operations under part 135 using unmanned aircraft systems for medical cargo deliveries with a part 119 air carrier certificate in the United States.

[FR Doc. 2020–15236 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–42]

Petition for Exemption; Summary of Petition Received; Causey Aviation Unmanned, Inc.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 4, 2020.

ADDRESSES: Send comments identified by docket number FAA–2020–0532 using any of the following methods:

- *Federal eRulemaking 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, 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 20590–0001, 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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 the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267–7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 9, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0532.

Petitioner: Causey Aviation Unmanned, Inc.

Sections of 14 CFR Affected: §§ 61.133; 91.7(a); 91.119(b) and (c); 91.121(a) through (c); 91.151(b); 91.203(a)(1); 135.25(a)(1) and (2); 135.63(c)(1) through (8); 135.63(d); 135.79(a)(1) through (3); 135.149(a); 135.161(a)(1) and (3); 135.161(b)(1); 135.203(b); 135.209(b); 135.243(b)(1) and (2); 135.267(a)(1) through (3); 135.267(c)(1) through (3); 135.293(h); and 135.415(b).

Description of Relief Sought: Causey Aviation Unmanned, Inc. petitions for an exemption to allow it to operate its Flytrex FTX–M600P to conduct on-demand commercial drone delivery operations under 14 CFR part 135 with a part 119 air carrier certificate.

[FR Doc. 2020–15235 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–41]

Petition for Exemption; Summary of Petition Received; AeroGuard Flight Training Center

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 4, 2020.

ADDRESSES: Send comments identified by docket number FAA–2020–0435 using any of the following methods:

- *Federal eRulemaking 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, 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 20590–0001, 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can

be reviewed at *http://www.dot.gov/privacy.*

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 the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Megan Blatchford, (202) 267–3896, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 9, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0435.

Petitioner: AeroGuard Flight Training Center.

Section of 14 CFR Affected: § 141.79(d)(1)(ii).

Description of Relief Sought: AeroGuard Flight Training Center (AeroGuard) seeks relief from § 141.79(d)(1)(ii) of Title 14 of the Code of Federal Regulations to allow flight instructors who have completed proficiency checks for AeroGuard's legacy Chinese Ab-Initio Program course to count these checks for AeroGuard's three separated replacement courses.

[FR Doc. 2020–15233 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–23]

Petition for Exemption; Summary of Petition Received; High Tide Aviation

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 4, 2020.

ADDRESSES: Send comments identified by docket number FAA–2019–0952 using any of the following methods:

- *Federal eRulemaking 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, 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 20590–0001, 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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 the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Brittany Newton, (202) 267–6691, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 9, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2019–0952.

Petitioner: High Tide Aviation.

Section(s) of 14 CFR Affected: § 135.297(d).

Description of Relief Sought: High Tide Aviation currently operates the King Air C–90 aircraft and requests an exemption from § 135.297(d) to permit a pilot to conduct semi-annual Instrument Proficiency Check Requirements concurrently with a King Air BE–200 Recurrent Training Course with Differences Training for the King Air C–90 in a full motion BE–200, Level-C flight simulator in substitution of conducting the required Instrument Proficiency Check Requirements in the actual aircraft.

[FR Doc. 2020–15234 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2020–0055]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

Under part 235 of title 49 of the Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that on June 18, 2020, Union Pacific Railroad Company (UPRR) petitioned the Federal Railroad Administration (FRA) seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA–2020–0055.

Applicant: Union Pacific Railroad Company, Mr. Neal Hathaway, AVP Signal Maintenance & Construction, 1400 Douglas Street MS/RM 0910, Omaha, NE 68179.

Specifically, UPRR requests permission to return a portion of a traffic control system to yard track on the Moffat Tunnel Subdivision, between milepost (MP) 3.64 and MP 4.68, in or near Denver, Colorado.

Returning Moffat Runner (Track 101) to yard track will allow a remote control locomotive pullback on Track 102 to be extended to DS005, at Federal Boulevard, stopping the pullback control 290 feet short of the insulated joints for signal 2W(S) CD.

In its petition, UPRR states the reason for the change is to allow its Operating Practices team to pull longer car cuts out of the yard, which will in turn help with congestion and conflict in the North Yard.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* Error! Hyperlink reference not valid.and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m.

to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Ave. SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by August 31, 2020 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2020–15186 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2019–0081]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

Under part 235 of title 49 of the Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that by a document dated July 3, 2020, Grenada Railroad, LLC (GRYR) petitioned the Federal Railroad Administration (FRA) seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA–2019–0081.

Applicant: Grenada Railroad, LLC, Barbara W. Wilson, President & CFO, 1515 S. Federal Highway, Suite 404, Boca Raton, FL 33432.

Specifically, GRYR seeks reconsideration of FRA's May 7, 2020, decision to deny GRYR's September 18, 2019, proposed discontinuance and removal of the automatic block signal (ABS) system located from milepost (MP) 403.0 near Southaven, MS, to MP 617.4 near Grenada, MS.

In its July 3, 2020, petition, GRYR states that reactivation of the ABS system, which has been out of service since 2014, is not justified by current rail operations, and the prohibitive costs of reactivation will require the use of capital which could be better spent on other projects to yield stronger safety benefits.

GRYR further states that under the ownership of RailUSA, GRYR has worked diligently and invested significantly to revitalize this long-neglected rail line, re-establish operations on the southern half of its system, and improve the safety and operations of the northern half of its system. The committed focus on rail safety and continued investment in infrastructure is expected to continue to improve the safety and operations of GRYR's main line and adjacent rail facilities.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Ave. SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by August 31, 2020 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2020–15189 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2020–0054]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this

document provides the public notice that on June 26, 2020, Virgin Trains USA—Florida, LLC (VTUS) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 270, System Safety Program. FRA assigned the petition Docket Number FRA–2020–0054.

VTUS requests relief from certain deadlines required under 49 CFR part 270 considering the company's temporary suspension of revenue passenger rail operations. Specifically, VTUS requests relief from the March 4, 2021, system safety program (SSP) plan filing requirement in § 270.201(a)(1). VTUS states that due to the COVID–19 public health emergency, VTUS suspended all passenger rail operations on March 26, 2020. A timeline for service restoration is currently unknown, but is not anticipated to precede the March 4, 2021, filing deadline for SSP. VTUS proposes to comply with part 270 as applicable to passenger railroads not currently in operation, and submit its SSP plan not less than 90 days before recommencing passenger operations.

Additionally, VTUS requests relief from the July 2, 2020, deadline in § 270.107(a)(3) for holding a preliminary meeting with directly affected employees. Due to the suspension of passenger rail operations on March 26, 2020, and that there are currently no directly affected employees to consult with, VTUS states that the July 2, 2020, deadline is not practicable. VTUS seeks to postpone such preliminary meeting until 120 days before recommencing passenger operations, allowing the company 30 days to incorporate comments from such meeting into its railroad consultation statement described in § 270.107(b).

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Ave. SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by August 31, 2020 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2020–15187 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2020–0028]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on March 17, 2020, CSX petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 225, Railroad Accidents/Incidents: Reports Classification, and Investigations. FRA assigned the petition Docket Number FRA–2020–0028.

Specifically, CSX requests a waiver from 49 CFR 225.25(h), which requires, in part, that monthly listings of employee reportable injuries, occupational illnesses, and fatalities be ''posted in a conspicuous location'' at each establishment where a railroad reasonably expects its employees to report during a 12-month period, and that employees ''have the opportunity to observe the posted list.'' CSX requests that in lieu of a paper copy of the listing, to make the required information available via a web portal that allows employees access to information from computer terminals and employees' personal electronic devices. CSX states that any employee who prefers a paper listing would have the option to request a hard copy of the listing from his or her supervisor.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Ave. SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by August 31, 2020 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2020–15188 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2018–0107 Notice 1]

Weldon, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Weldon, a Division of Akron Brass Company, has determined that certain LED 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 receipt of Weldon's petition.

DATES: Send comments on or before August 14, 2020.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and be submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the 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 comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/*. Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the docket. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000, (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. Overview

Weldon has determined that certain LED backup lamps 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.*

This notice of receipt of Weldon's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any Agency decision or other exercise of judgment concerning the merits of the petition.

II. Equipment Involved

Approximately 6,315 LED backup lamps manufactured between June 6, 2018, and June 25, 2018, are potentially involved.

III. Noncompliance

Weldon explains that the noncompliance is that the subject LED backup lamps do not meet the requirements for color as required by paragraph S14.4.1 of FMVSS No. 108. Specifically, the subject LED backup lamps, when tested in accordance with the Tristimulus Method, fell slightly outside the required boundaries for white light.

IV. Rule Requirements

Paragraph S14.4.1 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.

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. They have not been evaluated by the Agency and do not reflect the views of the Agency. Weldon described the subject noncompliance and stated their belief that the noncompliance is

inconsequential as it relates to motor vehicle safety.

In support of its petition, Weldon submitted the following reasoning:

1. Weldon first became aware of a potential issue with the white color parameters in late September 2018, when the customer observed that the vehicle backup lamps, when viewed side by side in production, appeared to have a slightly different color hue and then brought the issue to Weldon's attention and requested that Weldon test the color of the lamps. Samples were sent to a third-party laboratory for colorimetry testing. Thereafter, Weldon received the third-party laboratory's test results, which it analyzed and considered. The lamps at issue were tested using the proper colorimetry testing using the Tristimulus Method. An average of three readings of the lamps were taken at the design voltage. The LED functions were measured at t = 0 and t = 10 minutes. The result found that the supposed white color lamp fell slightly outside the required boundaries for white light.

2. 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. 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.

3. Weldon stated that NHTSA has long recognized that some deviations from the FMVSS pose little or no safety risk. In applying this recognition to particular situations, the Agency considers whether a deviation gives rise to ''a significantly greater risk than . . . in a compliant vehicle.'' *See* 69 FR 19897–990 (April 14, 2004). 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, 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.

4. In considering past petitions involving FMVSS No. 108, Weldon mentions that NHTSA has previously considered and found deviations from the standard that 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. NHTSA has found that deviation from the photometric parameters were inconsequential to safety when the overall brightness of the equipment was near to the required parameters to not be perceptible to the human eye. 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 (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). 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.'' *See* 66 FR 38341 (July 23, 2001). In fact, 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.* NHTSA views the UMTRI Report's findings to be ''mostly analogous to those of the signal lighting research.'' *Id.* 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. *See* 61 FR 1663 (Jan. 22, 1996). NHTSA has granted similar petitions for lamps that do not comply with photometric requirements in other slight ways.

5. Conversely, NHTSA has denied inconsequentiality petitions in cases where headlamps do not meet the minimum FMVSS requirements, thus, causing an increased safety risk. *See* 66 FR 38341 (July 23, 2001) (denying petition where points on the headlamp used for overhead sign illumination were substantially below the photometric minimum values, which impaired driver visibility). 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, 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. The backup lamps in question are still entirely visible (that is, the brightness of the tail lamps is not affected) 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. 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.

6. Weldon has not received any reports related to the performance of the white LED lamps from the field and is not aware of any accidents or injuries related to the issue.

Weldon concluded by expressing the belief 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.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject equipment that Weldon no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve equipment distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant equipment under their control after Weldon notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2020–15227 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0031; Notice 1]

Automobili Lamborghini Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Automobili Lamborghini has determined that certain model year (MY) 2015–2020 Lamborghini Huracan motor vehicles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, Reflective Devices, and Associated Equimpment.* Automobili Lamborghini filed a noncompliance report dated March 4, 2020, and subsequently petitioned NHTSA on March 25, 2020, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces receipt of Automobili Lamborghini's petition.

DATES: Send comments on or before August 14, 2020.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the 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 comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the docket. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. Overview

Automobili Lamborghini has determined that certain MY 2015–2020 Lamborghini Huracan motor vehicles do not fully comply with the requirements of paragraph S10.18.9.2 of FMVSS No. 108, *Lamps, Relective Devices, and Assoicated Equipment* (49 CFR 571.108). Automobili Lamborghini filed a noncompliance report dated March 4, 2020, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports,* and subsequently petitioned NHTSA on March 25, 2020, 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.*

This notice of receipt of Automobili Lamborghini's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any Agency decision or other exercise of judgment concerning the merits of the petition.

II. Vehicles Involved

Approximately 4,727 MY 2015–2020 Automobili Lamborghini Huracan motor vehicles manufactured between July 30, 2014, and February 26, 2020, are potentially involved.

III. Noncompliance

Automobili Lamborghini explains that the noncompliance is that the subject vehicles are equipped with headlamp assemblies that do not fully meet the requirements in paragraph S10.18.9.2 of FMVSS No. 108. Specifically, the horizontal aim of the lower beam can be adjusted due to the absence of a blanking cap over the beam's horizontal adjustment screw.

IV. Rule Requirements

Paragraph S10.18.9.2 of FMVSS No. 108 includes the requirements relevant to this petition. The standard requires that the headlamp not be adjustable in terms of horizontal aim unless the headlamp is equipped with a horizontal vehicle headlamp aiming device (VHAD). If the headlamp has a VHAD, it is set to zero.

V. Summary of Automobili Lamborghini's Petition

The following views and arguments presented in this section, V. Summary of Automobili Lamborghini's Petition, are the views and arguments provided by Automobili Lamborghini. They have not been evaluated by the Agency and do not reflect the views of the Agency. Automobili Lamborghini described the subject noncompliance and stated their belief that the noncompliance is inconsequential as it relates to motor vehicle safety.

Automobili Lamborghini stated that the horizontal aim adjustment of the subject beams is possible, due to the absence of a blanking cap over the beam horizontal adjustment screw. Demounting the luggage compartment liner, customers, with advanced technical knowledge, can reach the horizontal adjustment screw and make the horizontal adjustment by themselves; however, Automobili Lamborghini argues that this noncompliance is inconsequential to

motor vehicle safety for the following reasons:

1. First, the adjustment screw is hidden by the luggage liner when the vehicle's hood is open, so the screw is not visible.

2. Second, the Owner's Manual does not identify this screw, so no vehicle owner would ever need to try to search for and adjust the screw in question.

3. The only possibility to reach the adjustment screw without removing the luggage liner is through a small hole in the luggage liner using a long screwdriver, but without any possibility to see it and without any indication of how to do it.

4. Automobili Lamborghini is unaware of any accidents, injuries, or customer complaints related to the horizontal aim adjustment of the subject beams.

5. The issue was corrected in production during calendar week 15 (fifteen) of 2020.

Automobili Lamborghini concluded by expressing the belief 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.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that Automobili Lamborghini no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Automobili Lamborghini notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8).

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2020–15228 Filed 7–14–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2020–0030]

Minority Depository Institutions Advisory Committee

AGENCY: Office of the Comptroller of the Currency (OCC), Department of the Treasury.

ACTION: Notice.

SUMMARY: The OCC has determined that the renewal of the charter of the OCC Minority Depository Institutions Advisory Committee (MDIAC) is necessary and in the public interest. The OCC hereby gives notice of the renewal of the charter.

DATES: The charter of the OCC MDIAC has been renewed for a two-year period that began on June 23, 2020.

FOR FURTHER INFORMATION CONTACT: Beverly F. Cole, Deputy Comptroller for the Northeastern District and Designated Federal Officer, (212) 340–4001, Office of the Comptroller of the Currency, 340 Madison Ave. Fifth Floor, New York, NY 10173.

SUPPLEMENTARY INFORMATION: Notice of the renewal of the MDIAC charter is hereby given, with the approval of the Secretary of the Treasury, pursuant to section 9(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. The Comptroller of the Currency has determined that the renewal of the MDIAC charter is necessary and in the public interest to provide advice and information about the current circumstances and future development of minority depository institutions, in accordance with the goals established by section 308 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA), Public Law 101–73, Title III, 103 Stat. 353, 12 U.S.C. 1463 note, which are to preserve the present number of minority depository institutions, preserve the minority character of minority depository institutions in cases involving mergers or acquisitions, provide technical assistance, and encourage the creation of new minority depository institutions.

Brian P. Brooks,

Acting Comptroller of the Currency.

[FR Doc. 2020–15257 Filed 7–14–20; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID: OCC–2020–0028]

Mutual Savings Association Advisory Committee and Minority Depository Institutions Advisory Committee

AGENCY: Office of the Comptroller of the Currency, Department of the Treasury (OCC).

ACTION: Request for nominations.

SUMMARY: The OCC is seeking nominations for members of the Mutual Savings Association Advisory Committee (MSAAC) and the Minority Depository Institutions Advisory Committee (MDIAC). The MSAAC and the MDIAC assist the OCC in assessing the needs and challenges facing mutual savings associations and minority depository institutions, respectively. The OCC is seeking nominations of individuals who are officers and/or directors of federal mutual savings associations, or officers and/or directors of federal stock savings associations that are part of a mutual holding company structure, to be considered for selection as MSAAC members. The OCC also is seeking nominations of individuals who are officers and/or directors of OCC-regulated minority depository institutions, or officers and/or directors of other OCC-regulated depository institutions with a commitment to supporting minority depository institutions, to be considered for selection as MDIAC members.

DATES: Nominations must be received on or before September 8, 2020.

ADDRESSES: Nominations of MSAAC members should be sent to *msaac.nominations@occ.treas.gov* or mailed to: Michael R. Brickman, Deputy Comptroller for Thrift Supervision, 400 7th Street SW, Washington, DC 20219.

Nominations of MDIAC members should be sent to *mdiac.nominations@occ.treas.gov* or mailed to: Beverly F. Cole, Deputy Comptroller for the Northeastern District, 340 Madison Ave, Fifth Floor, New York, NY 10173.

FOR FURTHER INFORMATION CONTACT: For inquires regarding the MSAAC, Michael R. Brickman, Deputy Comptroller for Thrift Supervision: *msaac.nominations@occ.treas.gov* or (202) 649–5420.

For inquires regarding the MDIAC, Beverly F. Cole, Deputy Comptroller for the Northeastern District: *mdiac.nominations@occ.treas.gov* or (212) 340–4001.

SUPPLEMENTARY INFORMATION: The MSAAC and the MDIAC will be

administered in accordance with the Federal Advisory Committee Act, 5 U.S.C. App. 2. The MSAAC will advise the OCC on meeting the goals established by section 5(a) of the Home Owners' Loan Act, 12 U.S.C. 1464. The MSAAC will advise the OCC regarding mutual savings associations on means to: (1) Provide for the organization, incorporation, examination, operation and regulation of associations to be known as federal savings associations (including federal savings banks); and (2) issue charters therefore, giving primary consideration of the best practices of thrift institutions in the United States. The MSAAC will help meet those goals by providing the OCC with informed advice and recommendations regarding the current and future circumstances and needs of mutual savings associations. The MDIAC will advise the OCC on ways to meet the goals established by section 308 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, Public Law 101–73, Title III, 103 Stat. 353, 12 U.S.C. 1463 note. The goals of section 308 are to preserve the present number of minority institutions, preserve the minority character of minority-owned institutions in cases involving mergers or acquisitions, provide technical assistance, and encourage the creation of new minority institutions. The MDIAC will help the OCC meet those goals by providing informed advice and recommendations regarding a range of issues involving minority depository institutions. Nominations should describe and document the proposed member's qualifications for MSAAC or MDIAC membership, as appropriate. Existing MSAAC or MDIAC members may reapply themselves or may be renominated. The OCC will use this nomination process to achieve a balanced advisory committee membership and ensure that diverse views are represented among the membership of officers and directors of mutual and minority institutions. The MSAAC and MDIAC members will not be compensated for their time but will be eligible for reimbursement of travel expenses in accordance with applicable federal law and regulations.

Brian P. Brooks,

Acting Comptroller of the Currency.

[FR Doc. 2020–15259 Filed 7–14–20; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2020–29]

Mutual Savings Association Advisory Committee

AGENCY: Office of the Comptroller of the Currency (OCC), Department of the Treasury.

ACTION: Notice.

SUMMARY: The OCC has determined that the renewal of the charter of the OCC Mutual Savings Association Advisory Committee (MSAAC) is necessary and in the public interest. The OCC hereby gives notice of the renewal of the charter.

DATES: The charter of the OCC MSAAC has been renewed for a two-year period that began on June 23, 2020.

FOR FURTHER INFORMATION CONTACT: Michael R. Brickman, Designated Federal Officer, 202–649–5420, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Notice of the renewal of the MSAAC charter is hereby given, with the approval of the Secretary of the Treasury, pursuant to section 9(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2. The Comptroller of the Currency has determined that the renewal of the MSAAC charter is necessary and in the public interest in order to provide advice and information concerning the condition of mutual savings associations, the regulatory changes or other steps the OCC may be able to take to ensure the health and viability of mutual savings associations, and other issues of concern to mutual savings associations, all in accordance with the goals of Section 5(a) of the Home Owners' Loan Act, 12 U.S.C. 1464.

Brian P. Brooks,

Acting Comptroller of the Currency.

[FR Doc. 2020–15258 Filed 7–14–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treas.gov/ofac*).

Notice of OFAC Actions

On July 9, 2020, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Individuals:

1. HUO, Liujun (Chinese Simplified: 霍留军), Xinjiang, China; DOB 1952; Gender Male (individual) [GLOMAG].

   Designated pursuant to section 1(a)(ii)(C)(2) of Executive Order 13818 of December 20, 2017, "Blocking the Property of Persons Involved in Serious Human Rights Abuse or Corruption," 82 FR 60839, 3 CFR, 2017 Comp., p. 399, (E.O. 13818) for being a foreign person who is or has been a leader or official of an entity whose property and interests in property are blocked pursuant to E.O. 13818 as a result of activities relating to the leader's or official's tenure.

2. WANG, Mingshan (Chinese Simplified: 王明山), Xinjiang, China; DOB Jan 1964; POB Wuwei, Gansu, China; Gender Male (individual) [GLOMAG].

   Designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13818 for being a foreign person who is or has been a leader or official of an entity whose property and interests in property are blocked pursuant to E.O. 13818 as a result of activities relating to the leader's or official's tenure.

3. CHEN, Quanguo (Chinese Simplified: 陈全国), Xinjiang, China; DOB 1955; POB Pingyu, Henan, China; Gender Male (individual) [GLOMAG].

   Designated pursuant to section 1(a)(ii)(C)(1) of E.O. 13818 for being a foreign person who is or has been a leader or official of an entity, including any government entity, that has engaged in, or whose members have engaged in, serious human rights abuse relating to his tenure.

4. ZHU, Hailun (Chinese Simplified: 朱海仑), Xinjiang, China; DOB Jan 1958; POB Lianshui, Jiangsu, China; Gender Male (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being a foreign person who is responsible for or complicit in, or has directly or indirectly engaged in, serious human rights abuse.

Entity:

1. XINJIANG PUBLIC SECURITY BUREAU (Chinese Simplified: 新疆公安局) (a.k.a. PUBLIC SECURITY DEPARTMENT OF THE AUTONOMOUS REGION; a.k.a. PUBLIC SECURITY DEPARTMENT OF XINJIANG UYGAR AUTONOMOUS REGION; a.k.a. PUBLIC SECURITY DEPARTMENT OF XUAR; a.k.a. XINJIANG BUREAU OF PUBLIC SECURITY), Xinjiang, China [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being a foreign person that is responsible for or complicit in, or has directly or indirectly engaged in, serious human rights abuse.

Dated: July 9, 2020.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2020–15215 Filed 7–14–20; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0768]

Agency Information Collection Activity: Program of Comprehensive Assistance for Family Caregivers Improvements and Amendments Under the VA MISSION Act of 2018

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 14, 2020.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Brian McCarthy, Office of Regulatory and Administrative Affairs (10B4), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Brian.McCarthy4@va.gov.* Please refer to ''OMB Control No. 2900–0768'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Brian McCarthy at (202) 615–9241.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Program of Comprehensive Assistance for Family Caregivers Improvements and Amendments Under the VA MISSION Act of 2018, VA Form 10–10CG.

OMB Control Number: 2900–0768.

Type of Review: Revision of a currently approved collection.

Abstract: Pursuant to RIN 2900–AQ48, the Department of Veterans Affairs (VA) has proposed revisions to its regulations that govern VA's Program of Comprehensive Assistance for Family Caregivers (PCAFC). That rulemaking would make improvements to PCAFC and update the regulations to comply with section 161 of Public Law 115–182, the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, or the VA MISSION Act of 2018, which made changes to PCAFC's authorizing statute. The proposed changes would allow PCAFC to better address the needs of veterans of all eras and standardize the current program to focus on eligible veterans with moderate and severe needs.

This proposed rule—

- Would expand PCAFC to eligible veterans of all service eras, as specified.
- Would define new terms and revise existing terms used throughout the regulation. Some of the new and revised terms would have a substantial impact

on eligibility requirements for PCAFC (*e.g.,* in need of personal care services; need for supervision, protection, or instruction; and serious injury), and the benefits available under PCAFC (*e.g.,* financial planning services, legal services, and monthly stipend rate).

- Would establish an annual reassessment to determine continued eligibility for PCAFC.
- Would revise the stipend payment calculation for Primary Family Caregivers.
- Would establish a transition plan for legacy participants and legacy applicants who may or may not meet the new eligibility criteria and whose Primary Family Caregivers could have their stipend amount impacted by changes to the stipend payment calculation.
- Would add financial planning and legal services as new benefits available to Primary Family Caregivers.
- Would revise the process for revocation and discharge from PCAFC.
- Would reference VA's ability to collect overpayments made under PCAFC.

The background for PCAFC and this information collection resides in Title I of Public Law (Pub. L.) 111–163, Caregivers and Veterans Omnibus Health Services Act of 2010 (hereinafter referred to as ''the Caregivers Act''), which established section 1720G(a) of title 38 of the United States Code (U.S.C.) ''Assistance and Support Services for Caregivers.'' Section 1720G required VA to establish a Program of Comprehensive Assistance for Family Caregivers (PCAFC) of eligible veterans. The Caregivers Act also required VA to establish a Program of General Caregiver Support Services (PGCSS) that is available to caregivers of covered veterans of all eras. VA implemented the PCAFC and the PGCSS through its regulations in part 71 of title 38 of the Code of Federal Regulations (CFR). Through PCAFC, VA provides family caregivers of eligible veterans (as defined in 38 CFR 71.15) certain benefits, such as training, respite care, counseling, technical support, beneficiary travel (to attend required caregiver training and for an eligible veteran's medical appointments), a monthly stipend payment, and access to health care coverage (if qualified) through the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA). 38 U.S.C. 1720G(a)(3), 38 CFR 71.40.

In order to administer these benefits to caregivers, it is necessary that VA receive information about the nature of the benefit being sought and the persons who will be serving as primary or secondary family caregivers and receiving benefits. This information is collected with VA Form 10–10CG, which is currently approved under Office of Management and Budget (OMB) Control Number 2900–0768. Additional information will be collected by VA when a participating veteran provides required notice of a change of address and will be added to OMB Control Number 2900–0768.

VA Form 10–10CG

Affected Public: Individuals and households.

Estimated Annual Burden: 15,694 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Once annually.

Estimated Annual Number of Respondents: 62,776.

Veteran Change of Address Notification

Affected Public: Individuals and households.

Estimated Annual Burden: 542 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Annual Number of Respondents: 3,250.

By direction of the Secretary.

Danny S. Green,

PRA Clearance Officer, Office of Quality, Performance and Risk (OQPR), Department of Veterans Affairs.

[FR Doc. 2020–15247 Filed 7–14–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

42 CFR Part 2
Confidentiality of Substance Use Disorder Patient Records; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 2

[SAMHSA–4162–20]

RIN 0930–AA32

Confidentiality of Substance Use Disorder Patient Records

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule makes changes to the Department of Health and Human Services' (HHS) regulations governing the Confidentiality of Substance Use Disorder Patient Records. These changes were prompted by the need to continue aligning the regulations with advances in the U.S. health care delivery system, while retaining important privacy protections for individuals seeking treatment for substance use disorders (SUDs). SAMHSA strives to facilitate information exchange for safe and effective SUD care, while addressing the legitimate privacy concerns of patients seeking treatment for a SUD. Within the constraints of the authorizing statute, these changes are also an effort to make the regulations more understandable and less burdensome.

DATES: This final rule is effective August 14, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Deepa Avula, (240) 276–2542.

SUPPLEMENTARY INFORMATION:

Table of Contents

Acronyms

ADAMHA Alcohol, Drug Abuse, and Mental Health Administration
CEHRT Certified Electronic Health Record Technology
CFR Code of Federal Regulations
DEA Drug Enforcement Agency
DOJ Department of Justice
DS4P Data Segmentation for Privacy
EHR Electronic Health Record
FAX Facsimile
FDA Food and Drug Administration
FEMA Federal Emergency Management Agency
FHIR Fast Healthcare Interoperability Resources
FR Federal Register
HHS Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996
HIE Health Information Exchange
HIN Health Information Network
IHS Indian Health Service
MAT Medication-Assisted Treatment
NPRM Notice of Proposed Rulemaking
ONC Office of the National Coordinator for Health Information Technology
OTP Opioid Treatment Program
OUD Opioid Use Disorder
PDMP Prescription Drug Monitoring Program
QIO Quality Improvement Organization
TPO Treatment, Payment, and Health Care Operations
SAMHSA Substance Abuse and Mental Health Services Administration
SNPRM Supplemental Notice of Proposed Rulemaking
SUD Substance Use Disorder
U.S.C. United States Code

I. Background

The Confidentiality of Substance Use Disorder Patient Records regulations (42 CFR part 2) implement section 543 of the Public Health Service Act, 42 U.S.C. 290dd–2. The regulations were originally issued to ensure the confidentiality of patient records for the treatment of substance use disorder, at a time when there was no broader privacy and data security standard for protecting health care data. Under the regulations, a ''substance use disorder'' is a defined term, which refers to a cluster of cognitive, behavioral, and physiological symptoms indicating that an individual continues using a substance, despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For the purposes of part 2, this definition does not include tobacco or caffeine use.

The regulations were first promulgated as a final rule in 1975 (40 FR 27802) and amended thereafter in 1987 (52 FR 21796) and 1995 (60 FR 22296). On February 9, 2016, SAMHSA published a notice of proposed rulemaking (NPRM) (81 FR 6988) (the ''2016 proposed rule''), inviting comment on proposals to update the regulations, to reflect the development of integrated health care models and the growing use of electronic platforms to exchange patient information, as well as the new laws and regulations implemented since 1975, that more broadly protect patient data. At the same time, consistent with the authorizing statute, we (note that throughout this final rule, ''we'' refers to SAMHSA) wished to preserve the confidentiality protections that part 2 establishes for patient identifying information originating from covered programs, because persons with SUDs may encounter significant discrimination or experience other negative consequences if their information is improperly disclosed.

In response to public comments, on January 18, 2017, SAMHSA published a final rule (82 FR 6052) (the ''2017 final rule''), providing for greater flexibility in disclosing patient identifying information within the health care system, while continuing to protect the confidentiality of SUD patient records. SAMHSA concurrently issued a supplemental notice of proposed rulemaking (SNPRM) (82 FR 5485) (the ''2017 proposed rule'') to solicit public comment on additional proposals. In response to public comments, SAMHSA subsequently published a final rule on January 3, 2018 (83 FR 239) (the ''2018 final rule'') that provided greater clarity regarding payment, health care operations, and audit or evaluation-related disclosures, and provided language for an abbreviated prohibition on re-disclosure notice.

In both the 2017 and 2018 final rules, SAMHSA signaled its intent to continue to monitor implementation of 42 CFR part 2, and to explore potential future rulemaking to better address the complexities of health information technology, patient privacy, and interoperability, within the constraints of the statute. The emergence of the opioid crisis, with its catastrophic impact on individuals, families, and caregivers, and corresponding clinical and safety challenges for providers, has highlighted the need for thoughtful

updates to 42 CFR part 2. The laws and regulations governing the confidentiality of substance abuse records were originally written out of concern for the potential for misuse of those records against patients in treatment for a SUD, thereby undermining trust and leading individuals with SUDs not to seek treatment. As observed in the 1983 proposed rule, the purpose of 42 CFR part 2 is to ensure that patients receiving treatment for a SUD in a part 2 program ''are not made more vulnerable to investigation or prosecution because of their association with a treatment program than they would be if they had not sought treatment'' (48 FR 38763).

In recent years, the devastating consequences of the opioid crisis have resulted in an unprecedented spike in overdose deaths related to both prescription and illegal opioids including heroin and fentanyl,[1] as well as correspondingly greater pressures on the SUD treatment system, and heightened demand for SUD treatment services.[2] On August 26, 2019, SAMHSA published a Notice of Proposed Rulemaking (NPRM) (84 FR 44568) that proposed changes to the part 2 regulations that SAMHSA believed would better align with the needs of individuals with SUD and of those who treat these patients in need, and help facilitate the provision of well-coordinated care, while ensuring appropriate confidentiality protection for persons in treatment through part 2 programs.

SAMHSA requested public input of the proposed changes during a 60-day public comment period.

After consideration of the public comments received in response to the NPRM, SAMHSA is issuing this final rule substantially as proposed, with one caveat. On March 27, 2020, President Trump signed the Coronavirus Aid, Relief and Economic Security Act (''CARES Act'') into law (Pub. L. 116–136). The CARES Act was enacted to provide emergency assistance to individuals, families and businesses affected by the COVID–19 pandemic; to support the U.S. health care system; and to make emergency appropriations to the Executive Branch. Section 3221 of the CARES Act, Confidentiality and Disclosure of Records Relating to Substance Use Disorder, substantially amended several sections of the part 2 authorizing statute; specifically, sections 42 U.S.C. 290dd–2(b), (c) and (f), which specify requirements for patient consent, restrict the use of records in legal proceedings, and set penalties for violations of the statute, respectively.[3] The CARES Act provides far greater flexibility for patients and health care providers to share SUD records than presently allowed under 42 U.S.C. 290dd–2. Most notably, some sections in the new statute seek to align the part 2 confidentiality standards more closely with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The CARES Act requires HHS to update its regulations to implement these new statutory changes; therefore, HHS intends to publish a new NPRM and subsequently to issue a new final implementing rulemaking for the CARES Act in the future. Because both Congress and SAMHSA have sought to address many of the same barriers to information sharing by patients and among health care providers, we expect that the CARES Act implementing regulations will further modify several of the amendments adopted in this final rule.

The statutory timeline in § 3221 prevents the part 2-related provisions of the CARES Act from taking effect before March 27, 2021. In the interim, we believe that this final rule makes important changes that can help safeguard the health and outcomes of individuals with SUD, and specifically takes important first steps toward the greater flexibility for information sharing envisioned by Congress in its passage of § 3221 of the CARES Act. Thus, several of the regulatory amendments in this final rule will serve as interim and transitional standards, until regulations conforming to the CARES Act legislation can be promulgated.

II. Summary of the Major Provisions

Proposed modifications to 42 CFR part 2 were published as an NPRM on August 26, 2019 (84 FR 44568). After consideration of the public comments received in response to the NPRM, SAMHSA is issuing this final rule as follows:

Definitions (§ 2.11) revises the definition of ''Records'' to create an exception so that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with consent of the patient does not become a record subject to part 2 regulations merely because that part 2 information is reduced to writing by that non-part 2 provider.

Applicability (§ 2.12) revises the regulatory text to state that the recording of information about an SUD and its treatment by a non-part 2 provider does not, by itself, render a medical record subject to the restrictions of 42 CFR part 2, provided that the non-part 2 provider segregates any specific SUD records received from a part 2 program (either directly, or through another lawful holder).

Consent requirements (§ 2.31) revises consent requirements to allow patients to consent to the disclosure of their information to a wide range of entities without naming a specific individual to receive this information on behalf of a given entity, and includes special instructions applicable to consents for disclosure of information to information exchanges and research institutions. The final rule provides additional guidance, with regard to consent for disclosures for the purpose of care coordination and case management.

Prohibition on redisclosure (§ 2.32) revises the prohibition on redisclosure notices to clarify that non-part 2 providers do not need to redact information in a non-part 2 record regarding SUD and allows re-disclosure if expressly permitted by written consent of the patient or permitted under part 2 regulations.

Disclosures permitted with written consent (§ 2.33) expressly allows disclosure to specified entities and individuals for 18 types of payment and health care operational activities, including the 17 proposed activities and the addition of disclosures for the purpose of care coordination and case management.

Disclosures to prevent multiple enrollments (§ 2.34) revises disclosure requirements to allow non-opioid

[1] Mortality statistics published by the Centers for Disease Control and Prevention reflected a spike in the rate of opioid-related overdose deaths during the period from 2013–2017. See *https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w.* More recent data from the State Unintentional Drug Overdose Reporting System (SUDORS), showed that opioid-involved overdose deaths in 25 states slightly decreased from July–December 2017 to January–June 2018. However, even in that time period, increases in illicitly-manufactured fentanyl overdose deaths involving multiple drugs almost negated decreases in fentanyl analog deaths and prescription opioid-involved overdose deaths. *See https://www.cdc.gov/mmwr/volumes/68/wr/mm6834a2.htm*).

[2] With regard to heightened demand for, and pressures upon, SUD treatment services in the opioid epidemic, see for example, ''HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis,'' Department of Health and Human Services, October 26, 2017 (at *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html*); ''Today's Heroin Epidemic: More People at Risk, More Drugs Abused,'' Centers for Disease Control and Prevention, July 7, 2015 (at *https://www.cdc.gov/vitalsigns/heroin/*).

[3] Section 3221 of the CARES Act also added several new provisions to the Part 2 authorizing statute, codified at 42 U.S.C. 290dd–2(i), (j), and (k), regarding antidiscrimination, notification of breach and definitions, respectively.

treatment providers with a treating provider relationship to access central registries.

Disclosures to Prescription Drug Monitoring Programs (§ 2.36) creates new permissions to allow opioid treatment programs (OTPs) to disclose dispensing and prescribing data, as required by applicable state law, to prescription drug monitoring programs (PDMPs), subject to patient consent.

Medical Emergencies (§ 2.51) authorizes disclosures of patient information to another part 2 program or other SUD treatment provider during State or Federally-declared natural and major disasters.

Research (§ 2.52) permits research disclosures of part 2 patient data by a HIPAA covered entity to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule, for the purpose of conducting scientific research. The revised § 2.52 better aligns the requirements of part 2, the Common Rule, and the Privacy Rule around the conduct of research on human subjects, and seeks to streamline duplicative requirements for research disclosures under part 2 and the Privacy Rule in some instances. This final rule also revises § 2.52 to permit research disclosures to recipients who are covered by Food and Drug Administration (FDA) regulations for the protection of human subjects in clinical investigations (at 21 CFR parts 50 and 56).

Audit and evaluation (§ 2.53) clarifies that federal, state and local governmental agencies and third-party payers may conduct audits and evaluations to identify needed actions at the agency or payer level to improve care; that audits and evaluations may include reviews of appropriateness of medical care, medical necessity, and utilization of services; and that auditors may include quality assurance organizations as well as entities with direct administrative control over a part 2 program or lawful holder. Section 2.53 also updates language related to quality improvement organizations (QIOs), and allows for patient identifying information to be disclosed to federal, state, or local government agencies, and to their contractors, subcontractors, and legal representatives for audit and evaluations required by statute or regulation.

Orders authorizing use of undercover agents and informants (§ 2.67) amends the period for court-ordered placement of an undercover agent and informant within a part 2 program to 12 months and clarifies that the 12-month time period starts when an undercover agent or informant is placed in the part 2 program.

Use of Personal Devices and Accounts

This final rule preamble also provides guidance on how employees, volunteers and trainees of part 2 facilities should handle communications using personal devices and accounts, especially in relation to § 2.19 concerning disposition of records by discontinued programs. In § 2.11, the current regulation defines ''Records'' to include information relating to a patient that could include email and texts. In § 2.19, the regulation codifies the requirements for disposition of records from a discontinued part 2 program. These requirements state that records which are electronic must be ''sanitized'' within one year of the discontinuation of the part 2 program. This sanitization must render the patient identifying information non-retrievable in accordance with § 2.16 (security for records). Read together, current §§ 2.11, 2.16, and 2.19 could be interpreted to mean that, if an individual working in a part 2 program receives a text or email from a patient on his or her personal phone which he or she does not use in the regular course of employment in the part 2 program, and this part 2 program is discontinued, then the personal device may need to be sanitized. Depending on the policies and procedures of the part 2 program, this sanitization may render the device no longer useable to that individual. SAMHSA clarifies that this interpretation is not the intent of the regulations.

Although SAMHSA does not encourage patient communication through personal email and cell phones, we recognize that patients may make contact through the personal device or account of an employee (or volunteer or trainee) of a part 2 program, even if the employee (or volunteer or trainee) does not use such device or account in the regular course of their employment in the part 2 program. In such instances, SAMHSA wishes neither to convey that these devices become part of the part 2 record, nor that, if the part 2 program is discontinued, these devices must be sanitized. Instead, SAMHSA clarifies that, in the case that patient contact is made through an employee's (or volunteer's or trainee's) personal email or cell phone account which he or she does not use in the regular course of business for that part 2 program, the employee should immediately delete this information from his or her personal account and only respond via an authorized channel provided by the part 2 program, unless responding directly from the employee's account is required in order to protect the best interest of the patient.[4] If the email or text contains patient identifying information, the employee should forward this information to such authorized channel and then delete the email or text from any personal account. These authorized channels are then subject to the normal standards of sanitization under §§ 2.16 and 2.19 and any other applicable federal and state laws. SAMHSA believes that this process will both protect the employee's personal property and the confidentiality of the patient's records if the patient makes such unauthorized contact.

Following the proposed rule, SAMHSA received the following comments on its guidance concerning how employees, volunteers and trainees of part 2 facilities should handle communications using personal devices and accounts.

Public Comments

Many commenters supported the clarification on sanitizing personal devices. A few commenters noted that while this change will require education and monitoring, the clarification is important and valuable for part 2 programs to properly handle patient communication. Some commenters also noted that this clarification reduces burden for providers in rural areas where communication on authorized channels may not always be available.

SAMHSA Response

We appreciate comments in support of this clarification.

Public Comments

Some commenters had additional questions regarding the use of personal devices. One commenter requested guidance pertaining to the sanitizing of any other devices synchronized (''synced'') to personal accounts. A few commenters requested clarification as to whether deleting content from a personal account contravenes any state record retention requirements. One commenter requested clarification that this guidance applies only to personal devices, not professional devices from which EHRs are accessed. One commenter requested that ''incidental'' communication be defined more clearly. One commenter suggested that the rise of personal devices and changing nature of communication with patients may

[4] When the circumstances requiring a response from the employee's account due to the best interest of the patient have ended or otherwise permit, the messages should be forwarded to an authorized channel (if containing patient identifying information) and deleted.

warrant greater consideration from SAMHSA in future rulemaking.

SAMHSA Response

We appreciate questions from commenters to further clarify the use of personal devices. Providers should ensure that any patient communication accessible from synced devices is deleted from each device. Additionally, if a patient communication is contained solely on a personal device, providers should ensure that the communication is forwarded to and stored within an authorized channel prior to deleting the communication from the personal device. Providers concerned about state record retention requirements may include a note that the information has been forwarded to and stored within an authorized channel and deleted in compliance with 42 CFR part 2; however, this rule does not preempt more restrictive state record retention requirements Given that the definition of what constitutes incidental communication varies for providers in different settings (*e.g.,* rural), we decline to further define the phrase at this time. We appreciate the suggestion to further consider personal devices and will continue monitoring the issue.

The other sections in 42 CFR part 2 that are not referenced above are not addressed in this final rule nor were they discussed in the NPRM because SAMHSA is maintaining their content substantively unchanged from the 2017 and 2018 final rules.

III. Overview of Public Comments Received

SAMHSA received 684 public comment submissions on the proposed rule from medical and behavioral health care providers; combined medical/behavioral health care providers; third-party payers; privacy/consumer advocates; medical health care provider associations; behavioral health care provider associations; accrediting organizations; researchers; individuals (with no stated affiliation); attorneys (with no stated affiliation); health information technology (HIT) vendors; and state/local governments. The comments ranged from general support or opposition to the proposed provisions, to specific questions or comments regarding the proposed rules.

Some comments were outside the scope of or inconsistent with SAMHSA's legal authority regarding the confidentiality of SUD patient records. Likewise, other comments did not pertain to specific proposals made by SAMHSA in the NPRM. In some instances, commenters raised policy or operational issues that are best addressed through sub-regulatory guidance that SAMHSA will consider issuing subsequent to this final rule. Consequently, SAMHSA did not address these comments in this final rule.

IV. Final Modifications to 42 CFR Part 2 and Discussion of Public Comments

In this section of the final rule, SAMHSA explains the finalized revisions to the part 2 regulations and responds to public comments received. If a 42 CFR part 2 section is not addressed below, it is because SAMHSA did not propose changes to that part 2 provision and this final rule maintains the existing language in that section.

A. General Comments on the Proposed Rule

1. General Feedback on the Proposed Rule

a. General Support for the Proposed Rule

Public Comments

Many commenters expressed general support for the proposed rule. Among them, many believed that providers will be better able to offer a fully integrated model of care as a result, thereby allowing SUD services to be accessed more seamlessly, while increasing access to critically-needed SUD treatment. Other commenters expressed general support for the proposed rule because they saw it as protecting patient privacy, while making electronic health information sharing less burdensome and more efficient. Another set of commenters articulated support for SAMHSA's efforts to balance privacy protections with advances in the health care delivery system. Some commenters who expressed broad support for the proposed rule also suggested that HHS should carry out a comprehensive assessment of how well all the HHS patient privacy rules are currently working. A few commenters who expressed support for the proposed rule also expressed concern that it might not be flexible enough to support the rapid pace of care coordination that is needed to improve SUD patient care.

SAMHSA Response

SAMHSA appreciates the support for updating the part 2 regulations. This final rule is intended to modernize part 2 by continuing to align the regulations with advances in the U.S. health care delivery system. In general, SAMHSA aims to facilitate information exchange for safe and effective SUD care, while addressing the legitimate privacy concerns of patients seeking treatment for a SUD. But in recent years, the devastating consequences of the opioid crisis have resulted in an unprecedented spike in overdose deaths related to both prescription and illegal opioids, as well as correspondingly greater pressures on the SUD treatment system, and heightened demand for SUD treatment services. This final rule implements changes that SAMHSA believes will better align the needs of individuals with SUD and of the providers who treat them, thereby facilitating the coordination of care, while ensuring appropriate confidentiality protection for patients. SAMHSA will continue to monitor part 2 and its impact on both persons with SUD and providers, and will likewise continue to consider opportunities for further refinement of the rule in alignment with the provisions set forth in the CARES Act.

b. General Opposition to the Proposed Rule

Public Comments

Many commenters opposed the proposed rule, either without stating a specific reason, or else expressing that the proposed rule would constitute an invasion of patient privacy generally, or of their own personal privacy in particular. Many commenters opposed the rule on the grounds that it would exacerbate the stigma of substance use disorder, increase the potential for law enforcement access to patient records, deter people from seeking SUD treatment, and/or result in harm to SUD patients in several other ways, as through discrimination by health insurers. A different group of commenters expressed a competing concern about continuing administrative, financial and clinical barriers to better SUD care, and more effective coordination of care, under the proposed rule. Several of these commenters said that they believed the barriers could continue to endanger the safety of patients.

SAMHSA Response

SAMHSA wants to ensure that persons with SUD will have access to treatment services that include better coordination of care, and that deliver better quality of care and enhanced patient safety, while continuing to respect the legitimate privacy concerns of patients. The current final rule is consistent with this aim, and with the intent of the governing statute (42 U.S.C. 290dd–2) and regulations at 42 CFR part 2, which is to facilitate entry into SUD care by protecting the confidentiality of SUD patient records. SAMHSA believes that this final rule reflects an appropriate balancing of interests

toward achieving these ends. SAMHSA does not believe that this final rule will generally exacerbate stigma for persons with SUD, deter them from seeking treatment, or lead to other broadly negative downstream effects. SAMHSA will continue to consider opportunities for future refinements to the part 2 regulations, consistent with the provisions of the CARES Act.

c. General Request for Clarification and Guidance Related to Part 2

Public Comments

Several commenters broadly requested that SAMHSA provide clarification and guidance, in connection with confusing language and complexity in the proposed rule. Many other commenters said that educational outreach and guidance should be targeted to providers, to ensure that they understand the terms of the proposed rule.

SAMHSA Response

SAMHSA has provided further clarification through its responses to public comments in several sections of the final rule. SAMHSA recognizes the need for educational outreach both to persons with SUD and to providers in connection with the final rule, and is considering opportunities for further guidance and for carrying out related educational outreach. SAMHSA will continue to monitor the response to part 2 in the SUD treatment community, and will consider future refinements and further clarification to the part 2 rules as needed.

2. General Comments on Realigning the Part 2 Rule to the HIPAA Privacy Rule

Public Comments

Many commenters offered broad feedback that the privacy rules of 42 CFR part 2 are cumbersome and should be re-aligned with the HIPAA privacy rule. The commenters asserted that doing so could strengthen patient protections while allowing clinicians access to patient information needed to ensure patient safety and provide quality care. In a related vein, other commenters expressed support for legislation already introduced in Congress, aimed at more fully aligning the confidentiality standards of 42 CFR part 2 with the HIPAA privacy rule.

SAMHSA Response

SAMHSA noted the many comments that requested that SAMHSA align part 2 provisions with HIPAA where possible. In some instances, SAMHSA has attempted to do so in this final rule, to the extent that such changes were permissible under 42 U.S.C. 290dd–2. At the same time, part 2 and its governing statute are separate and distinct from HIPAA and its implementing regulations. Because of its targeted population, part 2 does establish more stringent federal protections than most other health privacy laws, including HIPAA.

Consistent with general comments about alignment of this regulation with HIPAA, SAMHSA has modified the definition of ''records'' (§ 2.11) and the applicability section (§ 2.12) to facilitate the disclosure of records from part 2 programs to non-part 2 providers for treatment purposes, while allowing the non-part 2 providers to engage in their own clinical encounters and record-keeping without fear that those activities will be subject to part 2. In addition, SAMHSA has offered revised guidance concerning the part 2 consent requirements (§ 2.31), in order to more explicitly allow patients to consent to disclosure of their records for the purpose of care coordination. As discussed below, SAMHSA is also modifying the regulatory text in § 2.33(b), to include disclosures for the purpose of care coordination and case management to the list of permitted activities. All these revisions will have the effect of more closely aligning confidentiality standards under part 2 with the HIPAA privacy rule.

As previously noted, on March 27, 2020, the President signed the CARES Act into law, and § 3221 of the CARES Act makes a significant modification to the authorizing statute for part 2, with the aim of realigning the part 2 rules more strongly with the HIPAA privacy rule. HHS anticipates releasing a new proposed rule within the next 12 months to implement § 3221 of the CARES Act. In the meantime, several of the regulatory amendments in this final rule will serve as transitional standards, until regulations fully conforming to the CARES Act legislation can be promulgated.

B. Definitions (§ 2.11)

SAMHSA is finalizing this section as proposed.

In the current regulation, ''Records'' is defined to mean ''any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient.'' In the 2017 final rule, SAMHSA noted that some commenters expressed confusion regarding what is considered unrecorded information (82 FR 6068); we, therefore, added parenthetical examples in an effort to clarify. But with the exception of these parenthetical examples, the basic definition for ''records'' under part 2 has remained the same since the 1987 final rule.

In section III.B. of the proposed rule [84 FR 44571] on ''Applicability'' (at § 2.12), SAMHSA discussed a proposed change to the restriction on disclosures under part 2, which would serve to clarify some record-keeping activities of non-part 2 providers that fall outside the scope of 42 CFR part 2. As explained in section III.B., the change was needed to facilitate communication and coordination between part 2 programs and non-part 2 providers, and to ensure that appropriate communications were not hampered by fear among non-part 2 providers of inadvertently violating part 2, as a result of receiving and reading a protected SUD patient record and then providing care to the patient.

SAMHSA proposed to make a conforming amendment to the § 2.11 definition of ''records,'' [84 FR 44571] by adding, at the end of the first sentence of the definition, the phrase, ''provided, however, that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient does not become a record subject to this part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider. Records otherwise transmitted by a part 2 program to a non-part 2 provider retain their characteristic as a ''record'' subject to this part in the possession of the non-part 2 provider, but may be segregated by that provider.''

The effect of the proposed amendment was to incorporate a very limited exception to the definition of ''records,'' such that a non-part 2 provider who orally receives information from a protected SUD record from a part 2 program may subsequently engage in an independent conversation with her patient, informed by her discussion with the part 2 provider, and record SUD information received from the part 2 program or the patient, without fear that her own records thereafter would become covered by part 2. The intent of this change was to better facilitate coordination of care between non-part 2 providers and part 2 programs, and to resolve lingering confusion among non-part 2 providers about when and how they can capture SUD patient care information in their own records, without fear of those records being subject to the confidentiality requirements of part 2.

The comments we received on the proposed amendments to § 2.11, and our responses, are provided below.

Public Comments

Many commenters supported the proposed change to the definition of records, saying that it would provide clarification as to which records are subject to part 2 protections; enable providers to take account of the entirety of a patient's health needs when determining a treatment plan; improve care coordination, especially among those with multiple medical concerns; better integrate primary and behavioral care for SUD patients; enhance patient safety; and potentially incentivize clinicians to treat patients with SUD. One commenter said the proposed definition of a record may be the most beneficial proposal in the rule, and noted that SAMHSA retains in its proposals the necessary protections against redisclosure by downstream recipients of part 2 records absent explicit patient consent. Another commenter expressed a desire to have more flexibility for care coordination across their delivery system for SUD patients, and observed that any changes to the definition of records requires balancing the need for increased protection for SUD treatment information with the need for access to care coordination.

SAMHSA Response

We thank the commenters for their support and reflections.

Public Comments

Several commenters supported the proposal but asked that SAMHSA expand the proposal beyond information conveyed orally to cover other forms of communications, including secure clinical messages (such as a secure web portal), which are common ways for providers to share information. One commenter said it would be confusing to allow orally communicated information to be covered under HIPAA while the same information conveyed via text would retain part 2 requirements. Other commenters said that imparting the oral requirement fails to appreciate workflow; that secure messaging is just as critical for patient safety; and that if information is received through electronic means, such as a Health Information Exchange, it should not become a record subject to part 2 if the non-part 2 provider includes it in his/her record.

A few commenters recommended that SAMHSA remove the word ''orally'' altogether from the proposed definition of records, to enable non-part 2 providers to document critical information received from a program regardless of the manner and mode in which it is provided. A few commenters suggested that non-part 2 providers should be allowed to document information such as medications if that information constitutes redisclosure with other providers for treatment purposes, without penalty hinging on whether the information is conveyed orally or by other means.

Others encouraged SAMHSA to provide greater emphasis on the ways that health information can be shared, used, and disclosed for the benefit of individuals' treatment, payment processes, and health care operations, and to further align definitions in the future such that part 2 providers could share pertinent information with non-part 2 providers.

SAMHSA Response

Although the change to the definition of ''records'' under § 2.11 applies to information disclosed orally by a part 2 program to a non-part-2 provider, this change will not create a disconnect under part 2 with regard to how other forms of communication by a part 2 program are treated. More specifically, the changes in § 2.12 of the rule on ''Applicability'' establish that records containing SUD information about a patient created by a non-part 2 provider will not be covered by part 2, unless any SUD record previously received from a part 2 program is incorporated into such records. Under § 2.12, segregation of the received record can be used by non-part 2 providers to ensure that their own created patient records can be distinguished from the received record, and thus will not become covered by part 2.

Taken together, the effect of the revisions to §§ 2.11 and 2.12 is to cause both oral and non-oral communications made by a part 2 program to a non-part 2 provider to be treated in the same way under the regulations. In each instance, the intent is to allow the part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2. Again, segregation of any received SUD record may be used by a non-part 2 provider to ensure that her own created records can be distinguished, and will therefore not become subject to part 2.

SAMHSA recognizes the importance of secure messaging and other forms of electronic communication and record-keeping in SUD care. SAMHSA nevertheless believes that the current revisions to §§ 2.11 and 2.12 offer an appropriate fix for allowing a limited transfer of information between part 2 programs and non-part 2 providers, subject to patient consent, in order to facilitate better coordination of care. SAMHSA will continue to consider opportunities for further re-alignment of part 2 requirements for the disclosure of SUD records for treatment, payment and health care operations in the future, to the extent permissible under the part 2 enabling statute, and in alignment with the provisions of § 3221 of the CARES Act.

Public Comments

One commenter requested that SAMHSA revise the definition of records to allow for oral communication between relevant entities without obtaining patient consent. The commenter said that requiring the consent of the patient in this instance is contrary to the stated intent of facilitating care coordination, and that SAMHSA should clarify that conversations between part 2 providers, non-part 2 providers and other appropriate third parties, including managed care organizations, should not require patient consent if undertaken for the purpose of treatment, payment or health operations, including care coordination and case management. Another commenter recommended exempting information about medications and laboratory results from the definition of ''records,'' thereby making it possible for a part 2 program to disclose such information without patient consent. That commenter asserted that such an exemption would help to enable a patient's [non-part 2] treatment providers to monitor for abuse, medication-seeking behavior, drug interactions, and possible diversion.

SAMHSA Response

SAMHSA believes that the current revisions to §§ 2.11 and 2.12 offer an appropriate fix for allowing a limited transfer of information between part 2 programs and non-part 2 providers, subject to patient consent, in order to facilitate better coordination of care. Other forms of communication between lawful holders of part 2 records are also permitted under the part 2 regulations with patient consent, consistent with the enabling statute. The revisions to §§ 2.11 and 2.12 reflect a balance of interests between ensuring robust privacy protection for part 2 program treatment records, while also pursuing patient safety, reduction of adverse events, and better coordination of care for persons with SUD. As discussed below, SAMHSA is also modifying the

regulatory text in § 2.33(b), to include disclosures for the purpose of care coordination and case management to the list of permitted activities. SAMHSA will continue to consider opportunities for further re-alignment of part 2 requirements for the disclosure of SUD records for treatment, payment and health care operations in the future, to the extent permissible under the part 2 enabling statute and in alignment with § 3221 of the CARES Act.

Public Comments

One commenter urged SAMHSA to further update the definitions of part 2 to make it clear that entities that are not directly delivering SUD treatment services, such as health plans and insurers, are explicitly not part 2 programs and are not non-part 2 providers. The commenter believes that making this concept more explicit would clarify confusion as to whether records created by health plans and insurers, independent of information disclosed to the health plan or insurer by a part 2 provider, are subject to part 2.

SAMHSA Response

SAMHSA appreciates this comment. Although outside the scope of the current rulemaking, SAMHSA will consider further clarifications to the definition of ''part 2 program'' in the future.

Public Comments

A few commenters expressed concern that the proposed revision to § 2.11 may create an-over-reliance upon oral communication and transcription, which they believe is inherently less accurate than electronic sharing of records; may further fragment patient records; and may encourage providers to avoid using electronic health records, especially for certain SUD information. Another commenter stated that the proposed exception for oral communications will prove difficult for part 2 programs and treating providers. The commenter said that compliance, privacy, and legal advisors will be hesitant to permit part 2 program staff to communicate with other health care providers orally due to concerns about misunderstandings or inaccurate transcriptions of oral communications, especially if there is no written record. Several commenters encouraged SAMHSA to recognize the need for accurate, complete, and efficient electronic exchange of information, such as through the new interoperable electronic health records that CMS and ONC seek to promote with their recent rulemaking, and move away from paper charts and manual faxing.

SAMHSA Response

Although the change to the definition of ''records'' under § 2.11 applies to information communicated orally by a part 2 program to a non-part-2 provider, this change will not result in a disconnect under part 2 with regard to how other forms of disclosure by a part 2 program are treated. Rather than creating a new reliance on oral communications over other methods of sharing records, SAMHSA believes that the change in §§ 2.11 and 2.12 will have the opposite effect, by making it more clear how a non-part-2 provider can receive and segregate an electronic or paper record from a part 2 program, without incurring the risk that any subsequent patient records directly created by the recipient provider will then become covered by part 2. For example, in the context of receiving an electronic part 2 record, such as a summary of care document, shared between interoperable EHR systems that meet DS4P standards, ''segregation'' might be carried out by segmenting the received SUD record so as to preserve the recipient's ability not to disclose it based on the sensitivity of its content. SAMHSA has been collaborating with both ONC and CMS in connection with their rulemaking efforts on the interoperability of electronic healthcare records, to ensure that health IT policies consider the impacts for part 2 providers and vice versa.

Public Comments

One commenter recommended that SAMHSA devote resources toward ensuring that patients understand the implications of the new policy. The commenter stated that when a patient consents to the release of a part 2 record to a non-part 2 provider, he or she must understand that they are not simply consenting to use of the information for a one-time conversation with the non-part 2 provider, but rather they are consenting to the information potentially becoming a part of his or her main medical record. The commenter believes that both the part 2 provider and the non-part 2 provider should make this clear, or else it could have a significant chilling effect on patients seeking SUD treatment, as those patients may believe that their right to confidentiality has been removed.

SAMHSA Response

SAMHSA appreciates this comment. We are considering opportunities for further guidance and patient and provider education, in connection with the new part 2 rule.

Public Comments

Several commenters opposed the changes proposed in the revised § 2.11. Some commenters explicitly opposed excluding from the definition of ''records'' any oral communication from a part 2 program that is received and later reduced to writing by a non-part 2 provider. These commenters said the ability to transmit SUD information orally would circumvent part 2, because the information would thereby lose its protection, and that patients who consent to sharing their records with a non-part 2 provider will not understand that information shared orally is not protected by part 2 in the recipient provider's records.

SAMHSA Response

Although the change to the definition of ''records'' under § 2.11 does apply to information communicated orally by a part 2 program to a non-part-2 provider, this change will serve to clarify, rather than to modify, the application of part 2 to patient records created by downstream non-part 2 providers. Neither the enabling statute, nor older versions of the part 2 regulations going back to 1987, ever intended the outcome that an oral communication made by a part 2 program to a non-part 2 provider, subject to patient consent, would make all subsequent clinical recordkeeping by the non-part 2 provider subject to the requirements of part 2.

The revisions to §§ 2.11 and 2.12 will help to clarify the longstanding balance of interests that part 2 requires, ensuring robust privacy protection for part 2 program treatment records, while also promoting patient safety, reduction of adverse events, and effective coordination of care for persons with SUD. Meanwhile, SAMHSA does acknowledge the importance of making sure that patients understand the contours of their part 2 privacy rights under the revised rule. Again, we are considering opportunities for further guidance and patient and provider education, in connection with the new part 2 rule, as well as in connection with other applicable laws, such as Jessie's Law, which was enacted as section 7051 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271). Jessie's Law calls for best practice development and dissemination around the display of an opioid use disorder diagnosis in health care records.

Public Comments

A few commenters said the proposed changes would allow sensitive information about a patient's substance use diagnosis or treatment that is included the general medical record to be shared much more broadly, putting the patient at greater risk of legal prosecution and discrimination. Commenters noted that while HIPAA may still protect the information, it permits much greater access to patient records by law enforcement, insurance companies, entities performing healthcare operations and courts. One commenter said that HIPAA is not sufficiently protective of health condition information that may be highly stigmatized or criminalized. Another said that patients must be able to access care for a SUD without fear of their highly sensitive information being transferred into HIPAA records that offer less protections. A few commenters said the changes will discourage people from seeking help or staying in treatment, including individuals living in areas that are already heavily policed. One commenter said that if any program or activity related to SUD knows that oral communications are no longer considered ''records'', then actions encompassing the identity, diagnosis, prognosis or treatment of any patient acquired in connection with the performance of that activity will be compromised, which runs counter to SAMHSA's claim of wanting to promote better quality of care for patients.

SAMHSA Response

SAMHSA believes that the revisions to §§ 2.11 and 2.12 offer an appropriate transitional fix for allowing a limited transfer of information between part 2 programs and non-part 2 providers, subject to patient consent, in order to facilitate better coordination of care. The revised provisions continue to require patient consent, even with oral communications. SAMHSA does not believe that this rule will create the downstream effects of substantially increased discrimination and stigma, nor of substantially decreased patient willingness to enter treatment.

Public Comments

A few commenters said the change to the definition of ''records'' under § 2.11 would be confusing to patients and providers, including one commenter who found the distinction between receiving an oral disclosure versus a disclosure of paper or electronic records unclear. The commenter noted that all of the part 2 protections cease to apply once a patient begins sharing information through a patient portal with a non-part 2 provider, since part 2 only applies to part 2 programs.

Several commenters said the proposed change would cause confusion for patients and providers in non-part 2 settings, by requiring different privacy standards for information disclosed orally versus in writing, different layers of protection for the same information, and a process to reconcile written records and oral communications in the receiving provider's system. Another commenter questioned how EHRs will distinguish among information received verbally, information received electronically and scanned, and information received in writing and then rewritten into the chart, which would presumably still enjoy part 2 protection.

SAMHSA Response

As discussed above, although the change to the definition of ''records'' under § 2.11 applies to oral disclosures made by a part 2 program to a non-part-2 provider, this change will not create a disconnect under part 2 with regard to how other forms of disclosure are treated. Notably, there is no requirement for a recipient, non-part 2 provider to reconcile a received oral disclosure with her own written records. More broadly, the revised §§ 2.11 and 2.12 create no new requirements for the use of EHRs, and no new risks for non-part 2 providers who are already using EHRs in the care of patients with SUDs. Rather, §§ 2.11 and 2.12 together make it clear that non-part 2 providers can create their own patient records, including SUD information, without that activity becoming subject to part 2. Any records previously received from a part 2 program may be segregated, in order to distinguish them from the independent recordkeeping activity of the non-part-2 provider recipient based on her own clinical encounters. And these basic parameters apply equally, regardless of what technology the non-part 2 provider is using to keep his or her own records. SAMHSA does note that using an EHR that supports data tagging and segmentation for privacy and consent management is one path by which a non-part 2 provider could comply with the final rule, particularly with regard to a received electronic record.

In order to address any confusion in the patient and provider communities, SAMHSA is considering opportunities for guidance and educational outreach, in connection with §§ 2.11 and 2.12 specifically, and the new part 2 rule more broadly.

Public Comments

One commenter asked if a patient must give written consent to ''verbal'' disclosure as well as to ''written or electronic'' disclosures, and if they could do so by checking distinct boxes.

SAMHSA Response

In general, the part 2 requirements for patient consent to a disclosure of his SUD treatment record by a part 2 program or lawful holder apply regardless of the medium by which any such disclosure is made. Under revisions in this final rule, a patient still must provide written consent in order for a part 2 program to orally share his or her part 2 information with a non-part 2 provider, unless an exception provided for under this Part applies.

Public Comments

One commenter asked for clarification on the difference between the terms, ''record,'' ''part 2 record,'' and ''part 2-covered record.'' The commenter said these terms are not defined. Likewise, another commenter said confusion remains about what constitutes a part 2 record and recommended that SAMHSA engage with stakeholders to inform future guidance that clarifies ambiguity.

SAMHSA Response

SAMHSA appreciates these comments. Although the term ''records'' is defined under § 2.11, the expressions ''part 2 record'' and ''part 2-covered record'' are not defined in the regulation. Broadly speaking, ''part 2 record'' and ''part-2 covered record'' both refer to an SUD patient record which is subject to the requirements of part 2, by virtue of originating from a part 2 program. In order to address any confusion in the patient and provider communities, SAMHSA is considering guidance and opportunities for educational outreach, in connection with §§ 2.11 and 2.12 specifically and the new part 2 rule more broadly.

Public Comments

One commenter said it was not clear whether certain facilities, like health centers, would benefit from the changes in §§ 2.11 and 2.12.

SAMHSA Response

SAMHSA appreciates this comment. SAMHSA will monitor the implementation of revised §§ 2.11 and 2.12 in the field, and will consider further guidance on the impact of the revisions to §§ 2.11 and 2.12, including with regard to disclosures by part 2 programs made to non-part 2 health centers.

Public Comments

One commenter appreciated the attempt to bring 42 CFR part 2 into alignment with other privacy rules but said there is still more work to be done to align with HIPAA and across agencies. The commenter said a paper-based workflow point of view is outdated and runs counter to burden-reduction efforts.

SAMHSA Response

SAMHSA appreciates these comments. SAMHSA will consider further revisions to the part 2 regulations in the future, particularly to implement § 3221 of the CARES Act. Several of the related CARES Act provisions will likely have the effect of more strongly aligning part 2 confidentiality standards with the HIPAA privacy rule.

Public Comments

A few commenters said that despite SAMHSA's statement that it does not intend to permit wholesale transcription of the patient's part 2 records into the primary care record, the proposed change may lead to that outcome, especially given the availability of text-to-speech technology applications. One commenter said SAMHSA had provided no parameters on what is permissible beyond the term ''clinical purpose,'' which could result in inappropriate and broad sharing of extensive and potentially damaging information, exposing SUD patients to legal prosecution and discrimination. Another commenter said that if SAMHSA finalizes the proposed amendment to § 2.11, it should include limits on the quantity of information to be transcribed, a clear prohibition on the use of text-to-speech technology for the purposes of this provision, and a requirement that the primary care practitioner counsel the patient on the privacy implications of consenting to such a disclosure, including the ways that HIPAA is less protective of patient privacy than part 2 or applicable state privacy laws.

One commenter applauded SAMHSA's inclusion of language in the preamble addressing the possibility that a non-part 2 provider might transcribe extensively from a part 2 record without having a clinical purpose for doing so and the agency's explicit statement that this is not the intent of the proposal. The commenter urged SAMHSA to incorporate this concept into regulatory text so that non-part 2 providers and other lawful holders are on notice that the intent behind SAMHSA's revised definition of ''records'' is to facilitate a treatment discussion between a non-part 2 provider and a patient and not a loophole to circumvent patient privacy and consent. The commenter urged that both §§ 2.11 and 2.12 reference this principle, and asked that § 2.11 specifically note that oral communications from part 2 providers to payers or other third parties are not to be used as the basis of the creation of separate record streams for patients. The commenter also said that SAMHSA should make clear in regulations that its intent behind the revisions to §§ 2.11 and 2.12 is to promote a clinical purpose, such as to allow a treatment note based on a direct clinical encounter with the patient. Short of this clarification, the commenter said SAMHSA should not revise the definition of records to exclude oral communications.

Another commenter suggested that SAMHSA provide sub-regulatory guidance and narrative examples that illustrate acceptable practices regarding the extent of transcription and/or documentation permitted from this change.

SAMHSA Response

As we explained above, the effect of the revision in § 2.11 is to incorporate a very limited exception to the definition of ''records,'' such that a non-part 2 provider who orally receives a protected SUD information from a part 2 program may subsequently engage in an independent conversation with her patient, informed by her discussion with the part 2 provider, and record SUD information received from the part 2 program or the patient, without fear that her own records for that patient thereafter would become covered by part 2. This provision will not immunize the misconduct of a non-part 2 provider who engages in the wholesale transcription of a received SUD patient record, without her own direct patient encounter and without clinical purpose.

SAMHSA will consider issuing future guidance on acceptable practices regarding the extent of transcription and/or documentation permitted under §§ 2.11 and 2.12 if we find it is necessary.

Public Comments

One commenter said the proposed revisions to the definition of ''records'' and ''applicability'' are vague and do not provide any meaningful or clear guidance on what can be added to a medical record without triggering the requirements of 42 CFR part 2. Another commenter asked for clarification as to whether part 2 redisclosure limitations apply when a treating non-part 2 provider reviews the part 2 program record, transcribes information from that record which has been validly shared pursuant to patient consent, and then inserts it into his or her own treatment record. The commenter asked SAMHSA to confirm that doing so would avoid application of part 2 to the treating provider's record and to broaden the exception to permit portions, summaries, or other extractions from the record to be redisclosed without consent.

SAMHSA Response

As discussed above, the preamble and revisions to §§ 2.11 and 2.12 speak with specificity to the circumstances in which a non-part 2 provider can receive and hold a treatment record from a part 2 program, while nevertheless being able to create her own patient records without fear that these will become covered by part 2. Taken together, the effect of the revisions to §§ 2.11 and 2.12 is to allow a part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2. Again, segregation of any received SUD record may be used by a non-part 2 provider to ensure that her own created records can be distinguished and will therefore not become subject to part 2.

Consistent with the foregoing explanation, SAMHSA believes that the revised §§ 2.11 and 2.12 strike the appropriate balance in describing how part 2 will apply in these situations.

Public Comments

One commenter asked whether patient SUD treatment information obtained and then recorded by a part 2 program from a non-part 2 provider could be exempt or outside the definition for a part 2 record.

SAMHSA Response

No, that information would still receive part 2 protection. There is nothing in the final rule that modifies the basic definition of ''records'' under § 2.11, as this applies to a part 2 program. Section 2.11 states, in pertinent part, that ''Records means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient.''

C. Applicability (§ 2.12)

SAMHSA is finalizing this section as proposed.

In the 1987 final rule, SAMHSA broadly established that the restrictions on disclosure under 42 CFR part 2 would apply to any alcohol and drug abuse information obtained by a federally assisted alcohol or drug abuse program. As explained in 1987, by limiting the applicability of 42 CFR part 2 to specialized programs—that is, to those programs that hold themselves out as providing and which actually provide alcohol or drug abuse diagnosis, treatment, and referral for treatment—the aim was to simplify the administration of the regulations, but without significantly affecting the incentive to seek treatment provided by the confidentiality protections. Limiting the applicability of 42 CFR part 2 to specialized programs was intended to lessen the adverse economic impact of the regulations on a substantial number of facilities which provide SUD care only as incident to the provision of general medical care. The exclusion of hospital emergency departments and general medical or surgical wards from coverage was not seen as a significant deterrent to patients seeking assistance for alcohol and drug abuse. SAMHSA's experience in the more than 30 years since 1987 has been consistent with this expectation.

The 2017 final rule elaborated on this policy, by establishing that the disclosure restrictions on SUD patient records would extend to individuals or entities who receive such records either from a part 2 program or from *another lawful holder.* See 42 CFR 2.12(d)(2)(i)(C). As explained in the 2017 final rule, a ''lawful holder'' of patient identifying information is an individual or entity who has received such information as the result of a part 2-compliant patient consent, or as a result of one of the exceptions to the consent requirements in the statute or implementing regulations (82 FR 6068). Thus, the effect of the 2017 rule was to expand the scope of application for part 2 confidentiality, by ensuring that records initially created by a part 2 program would remain protected under 42 CFR part 2 throughout a chain of subsequent re-disclosures, even into the hands of a downstream recipient not itself a part 2 program. The reason for the 2017 change was, once again, to avoid any deterrent effect on patients seeking specialized SUD care through part 2 treatment programs, by virtue of the patient records from those programs losing their part 2 confidentiality protection following a disclosure downstream to other ''lawful holder'' recipients of those records (81 FR 6997).

Although that policy was established in the 2017 final rule, specifically in § 2.12(d)(2)(i)(C), there remains some confusion within the provider community about what information collected by non-part 2 entities is (or is not) covered by the part 2 restrictions on re-disclosure. When SAMHSA expanded the reach of the Applicability provision in 2017, the intent was not to change the policy established in the 1987 rulemaking, nor to make the records of non-part 2 entities (such as some primary care providers) directly subject to 42 CFR part 2, simply because information about SUD status and treatment might be included in those records. Rather, the intent underlying the 2017 provision was to clarify the applicability of 42 CFR part 2 in a targeted manner, so that records initially created under the protection of part 2 would continue to be protected following disclosure to downstream recipients. In doing so, SAMHSA sought to encourage individuals to enter into SUD treatment through part 2 programs, by strengthening the confidentiality protection for records that originate from those programs. Implicit in SAMHSA rulemaking since 1987 has been the pursuit of a balance of policy interests: On the one hand, consistent with the Congressionally stated purpose of the drug abuse confidentiality statute, to encourage entry into SUD treatment by ensuring that the records of treatment through a part 2 program would not be publicly disclosed, and on the other hand, to reduce the adverse impact of part 2 burdens on general medical care providers and facilities and on patient care.

In the wake of the nation's opioid epidemic and continuing trends related to alcohol use disorder and cannabis use disorder, it has become increasingly important for primary care providers and general medical facilities not covered by 42 CFR part 2 to be able to carry out treatment and health care operations that sometimes involve creating new records that mention SUD status and care. Such records and activities are not covered by 42 CFR part 2. However, coordination of care between part 2 programs and non-part 2 providers would involve the disclosure of SUD records and information by the former to the latter. Under the current 42 CFR part 2 regulation, such disclosures of records by a part 2 program to a non-part 2 provider do not render all subsequent records on SUD caretaking activity undertaken by the non-part 2 provider subject to the part 2 regulation. For example, when a non-part 2 provider is directly treating her own patient, and creates a record based on her own patient contact that includes SUD information, then that record is not covered by part 2.

Nevertheless, SAMHSA recognizes that there may be significant confusion or misunderstanding as to the applicability of part 2 rules to non-part 2 providers. This results in increased burden on non-part 2 providers, and the potential for impaired coordination of care for patients, which could be life threatening, for example, if an affected patient has an opioid use disorder. Although the existing text of 42 CFR 2.12 (d)(2)(i)(C) on Applicability does not compel these results, SAMHSA's experience in recent years has demonstrated the need for clearer regulatory language, to better delineate the records of non-part 2 entities which are not covered by the 42 CFR part 2 rules.

Based on the above considerations, SAMHSA proposed to add a new § 2.12(d)(2)(ii), to better clarify that a non-part 2 treating provider's act of recording information about a SUD and its treatment would not make that record subject to 42 CFR part 2. SUD records received by that non-part 2 entity from a part 2 program are subject to part 2 restrictions on redisclosure of part 2 information by lawful holders, including redisclosures by non-part 2 providers. However, the records created by the non-part 2 provider in its direct patient encounter(s) would not be subject to part 2, unless the records received from the part 2 program are incorporated into such records. Segregation or segmentation of any part 2 records previously received from a part 2 program can be used to ensure that new records (*e.g.,* a treatment note based on a direct clinical encounter with the patient) created by non-part 2 providers during their own patient encounters would not become subject to the part 2 rules.

SAMHSA believed that this addition will further clarify the 2017 revisions, by affirming that the independent record-keeping activities of non-part 2-covered entities remain outside the coverage of 42 CFR part 2, despite such providers' (segregated) possession, as lawful holders, of part 2-covered records. The part 2 disclosure restrictions only apply to SUD patient records originating with part 2 providers. Such part 2 originating records are subject to the part 2 limitations on use and disclosure as they move through the hands of other ''lawful holders'' and part 2 programs. Even where part 2 does not apply to a patient record created by a non-part 2 provider following a direct patient encounter, that record will nevertheless be subject to the HIPAA Privacy Rule.

One means by which non-part 2 treating providers could benefit from the above proposal would be through the segregated storage of part 2-covered SUD records received from a part 2 program or other lawful holder. In the context of a paper record received from a part 2 program, the proposed requirement could be met by the ''segregation'' or ''holding apart'' of these records; in the context of electronic records from a part 2 program, the proposed requirement could be met by logical ''segmentation'' of the record in the electronic health record (EHR) system in which it is held. As under the current rule, when a non-part 2 entity receives a protected SUD record from a part 2 program or other lawful holder, the received record is subject to the heightened confidentiality requirements under part 2. ''Segregating'' the received record, whether by segmenting it or otherwise labeling or holding it apart, would allow the recipient entity to identify and keep track of a record that requires heightened protection.

Under both the proposed and the current text of part 2, the lawful holder recipient entity remains subject to part 2 re-disclosure restrictions with regard to the part 2 record, whether or not the recipient entity is able to segregate it. But ''segregating'' allows the recipient entity both to keep track of the part 2 records, and readily distinguish them from all the other patient records that the entity holds which are not subject to part 2 protection. As mentioned above, ''segregating'' the part 2 record may involve physically holding apart any part 2-covered records from the recipient's other records, which would be quite feasible in the case of a received paper record or an email attachment containing such data. Alternately, ''segregating'' can involve electronic solutions, such as segmenting an electronic SUD patient record received from a part 2 program by use of electronic privacy and security tags such as those in an EHR platform leveraging the HL7 Data Segmentation for Privacy (DS4P) standard, in which segmentation is carried out electronically based on the standards of DS4P architecture (discussed further below). Either of these methods for ''segregating'' part 2 covered records is a satisfactory way for the recipient entity to keep track of them, and to distinguish them from all the other patient records that the entity holds which are not subject to part 2 protection. We note that ''segregating'' a received part 2 record does not require the use of a separate server for holding the received part 2 records. We do not intend this rule to result in the creation of separate servers or health IT systems for part 2 documents. Our policy is intended to be consistent with existing technical workflows for data aggregation, storage, and exchange.

One concern that the proposed provision raises is the possibility that a non-part 2 provider might transcribe extensively from a part 2 record without having a clinical purpose for doing so. This, however, is not the intent of the provision. Briefly, the intent is to allow a non-part 2 provider to receive SUD information about a patient from a part 2 program, and then to engage in a treatment discussion with that patient, informed by that information, and then be able to create her own treatment records including SUD content, without the latter becoming covered by part 2. This level of flexibility is needed in order to improve coordination of care efforts, and to save lives. It is not SAMHSA's intent to encourage a non-part 2 provider to abuse the rules, by transcribing extensively from a conversation with a part 2 program or from a received part 2 record when creating her own records, without having a clinical purpose for doing so. Our intent is to expressly permit an avenue of communication, with patient consent, between a part 2 program and non-part 2 provider to facilitate better coordination of care, without automatically triggering application of the rule to the independent records of non-part 2 providers.

In the 2017 final rule, SAMHSA responded to several public comments about data segmentation issues connected to 42 CFR part 2. We acknowledged then that although significant challenges exist for data segmentation of SUD records within some current EHR systems, SAMHSA has led the development of use-case discussions related to the technical implementation of the DS4P standard and recently contributed to the development of the Fast Healthcare Interoperability Resources (FHIR) implementation guide for Consent2Share.[5] We believe that the existing health IT standards which enable data tagging and data segmentation and which support the SAMHSA Consent2Share tool are important to help advance the needs of part 2 providers and providers across the care continuum. SAMHSA recognizes and encourages the further development of DS4P standards, and the adoption by developers and vendors of EHR systems that meet those standards. The final revisions at § 2.12 do not, however, impose on non-part 2 entities any new requirement for data segmentation as a practice, nor do they establish any new standards or requirements for EHR technology. SAMHSA considered including, in the proposed rule, the policy option of defining ''segmented'' and ''segmentation'' under 42 CFR part 2, in order to offer greater clarity about what these terms mean under the rule. Segmentation involves technical capabilities and implementation for tagging and consent management, as well as technical specifications to accurately effect disclosure or non-disclosure of data based on federal, state, and local jurisdictions privacy restrictions and patient consent. This requires both technical specifications as well as supporting policies and governance for the treatment of sensitive data that is tagged. The latter is essential for effective segmentation, and segmentation is not achievable solely via adoption of a specific standard, nor is part 2 the only applicable use case for segmentation. For these reasons, we decided not to define segmentation for the purposes of this rulemaking, as such a definition might have unforeseen technical ramifications for EHR and HIE systems implementation in the future. In addition, SAMHSA believes this policy should be flexible, to allow providers with different operational standards and capabilities to implement the policy with regard to segregation or segmentation in the least burdensome way to their practices, while still maintaining confidentiality of patient records subject to part 2. Nevertheless, using health IT to support data tagging and data segmentation for privacy and consent management is one path that a provider could use to support their effort to meet part 2 requirements, including those described in the proposed rule.

In addition to the proposed revision to 42 CFR 2.12(d) above, SAMHSA proposed conforming changes to the regulatory text of several other sections of 42 CFR 2.12, to provide further clarification of the applicability of part 2 restrictions on patient records.

In § 2.12(a), SAMHSA proposed to change the text to reflect that the restrictions on disclosure apply to ''any records,'' rather than to ''any information, whether recorded or not.'' We also proposed a conforming change to § 2.12(a)(ii), to indicate that the restrictions of this part apply to any records which ''contain drug abuse information obtained . . .'' or ''contain

[5] ''Consent2Share FHIR Profile Design.docx'' can be accessed at *https://gforge.hl7.org/gf/project/cbcc/frs/.*

alcohol abuse information obtained . . . .'' Taken together, these changes are congruent with the amendment to § 2.12(d) and help to make it clear that part 2 applies to ''records'' (as defined under § 2.11).

In § 2.12(e)(3), SAMHSA proposed to change the text to reflect that the restrictions on disclosure apply to the recipients ''of part 2-covered records,'' rather than to the recipients ''of information.'' This proposed change is congruent with the proposed amendment to § 2.12(d) and would help to make explicit that downstream restrictions on re-disclosure by non-Part 2 entities are tied to protected records which originate from a part 2 program in the first instance. SAMHSA believes that this proposed conforming change is important, because it would further establish that the re-disclosure burden for non-part 2 entities as lawful holders ties specifically to the protected records that they receive from a part 2 program, and not to any other records that the non-part 2 entity creates by itself, regardless of whether the latter might include some SUD-related content.

In § 2.12(e)(4), SAMHSA likewise proposed a conforming change to the text, by adding language to reflect that a diagnosis prepared by a part 2 program for a patient who is neither treated by nor admitted to that program, nor referred for care elsewhere, is nevertheless covered by the regulations in this part. The change to the regulatory text is for clarity, to ensure that this section could not be misread as applying directly to the activities of a non-part 2 entity or provider.

Similarly, and congruent with the above conforming changes, SAMHSA also proposed to modify the definition of ''Records'' in § 2.11 as discussed in Section III.A. above and to modify and streamline the language in § 2.32 as discussed in Section III.D. below. Readers are referred to those sections of the proposed rule for specifics on those proposals and the rationales for such proposed policies.

The comments we received on the proposed amendments to § 2.12, and our responses, are provided below.

Public Comments

Many commenters supported our proposal to clarify that a non-part 2 treating provider's act of recording information about a SUD and its treatment would not make that record subject to 42 CFR part 2, stating that, since the information disclosed to non-part 2 providers will still be governed and protected by HIPAA, the proposal strikes the appropriate balance between allowing for coordination of care and encouraging patients to seek treatment for a SUD by ensuring patient records remain confidential. Another commenter said SAMHSA's proposal to allow non-part 2 treating providers to record information about a SUD and its treatment during direct patient encounters without subjecting the information and the record to part 2 would reduce confusion and burden on providers. Several commenters also stated that the policy could help facilitate meaningful communication between part 2 programs and non-part 2 providers. One commenter specifically noted that patients are often surprised when they find out that their records cannot be shared between providers, and this policy may alleviate that concern. Another commenter specifically noted that this proposal is necessary because the schema of DS4P and specifically the Consent to Share tool that SAMHSA proposed in the 2017 Final Rule does not work within a shared electronic health record, but this proposal could.

SAMHSA Response

We thank the commenters for their support.

Public Comments

One commenter, while supporting the proposal, asked for further clarification and guidance on the implementation of the proposed changes so that providers can assure compliance with the regulations.

SAMHSA Response

SAMHSA thanks the commenter for this support. SAMHSA will consider issuing implementation guidance for providers in connection with this rule.

Public Comments

Several commenters opposed our proposal to clarify that a non-part 2 treating provider's act of recording information about a SUD and its treatment would not make that record subject to 42 CFR part 2, stating that confidentiality is imperative for building trust, establishing rapport, and creating a therapeutic environment in which individuals are able to explore their mental health needs and substance use history. Some commenters argued that this proposal would deter treatment, infringe the patient-provider relationship, increase stigma, and lead to criminalization. One commenter specifically noted that recent research suggests that healthcare providers perceive patients with documented substance use more negatively than patients with other documented health conditions, and widely sharing records could lead to negative impacts on care.

SAMHSA Response

SAMHSA believes that the revisions to §§ 2.11 and 2.12 offer an appropriate transitional fix for allowing a limited transfer of information between part 2 programs and non-part 2 providers, subject to patient consent, in order to facilitate better coordination of care. The revised provisions continue to require patient consent for disclosure of a patient record by a part 2 program for the purpose of treatment, even in the case of oral disclosures. SAMHSA does not believe that these regulations will create downstream effects of substantially increased discrimination and stigma, or of substantially decreased patient willingness to enter into treatment.

Public Comments

One commenter opposed the proposal because of the belief that it made a problematic and stigmatizing assumption that patients have not disclosed their treatment information to their providers. Alternatively, another commenter stated that the proposal would not fix the existing challenges for patient safety, because providers may not be aware of a patient's history of opioid use disorder when treating the patient for other conditions, even if those other conditions are related to the SUD.

SAMHSA Response

SAMHSA believes that the revisions to §§ 2.11 and 2.12 will help to improve the coordination of care between part 2 programs and non-part 2 providers, as well as by non-part 2 providers who receive an SUD patient record disclosed to them by a part 2 program. Rather than making a stigmatizing assumption that patients have not disclosed their SUD treatment information to their [non-part 2] providers, the revisions to §§ 2.11 and 2.12 are intended to facilitate both patients and providers in carrying out exactly those disclosures. Although SAMHSA anticipates that these revisions will help to enhance quality of care efforts and to improve patient safety, it is unlikely that any single policy reform under part 2 will fully resolve the adverse events and safety problems associated with the opioid epidemic. SAMHSA will continue to consider a range of other policies and interventions to address the public health impact of the opioid epidemic in the future.

Public Comments

Several commenters asked for clarification regarding the recording of part 2 information by a non-part 2 provider in a patient's record. One commenter stated that the proposal was too vague and did not provide any meaningful or clear guidance on what can be added to a medical record without triggering the requirements of 42 CFR part 2. Another commenter asked if the proposal would result in the entire record being enveloped in part 2. A few commenters asked us to clarify whether a non-part 2 provider's act of copying and pasting relevant information from a patient's part 2 program record into a non-part 2 record would constitute the ''recording'' of SUD information and thus preclude the application of part 2 to the non-part 2 record. Commenters requested detailed guidance to ensure part 2 programs and treating providers are aware of the permissible means to transfer SUD information. One commenter specifically requested guidance on the nature and extent of data that can arise from treatment discussions informed by part 2 data or clinically relevant transcription and whether data segmentation/tagging of such a non-part 2 record is required. The commenter also urged more evaluation and real-world implementation testing with respect to the implementation, standards, and technology issues associated with both clarifications.

SAMHSA Response

As discussed above, we believe both the preamble and revisions to §§ 2.11 and 2.12 speak with specificity to the circumstances in which a non-part-2 provider can receive and hold a treatment record from a part 2 program, while nevertheless being able to create her own subsequent patient records without fear that these will become covered by part 2. Notably, there is nothing in the final rule that would cause an entire record to be ''enveloped in part 2,'' any more so than is the case now. Again, the effect of the revisions to §§ 2.11 and 2.12 is to allow the part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2. Segregation of any received SUD record may be used by a non-part 2 provider to ensure that her own created records can be distinguished, and will therefore not become subject to part 2.

Taken together, SAMHSA believes that the revised §§ 2.11 and 2.12 strike the appropriate balance in describing how part 2 will apply in these situations. SAMHSA is considering future guidance to clarify the requirements of §§ 2.11 and 2.12 for providers, and SAMHSA will continue to collaborate with other federal agencies in regard to technology implementation and standard-setting that touches on part 2 records.

Public Comments

One commenter stated opposition to any limitations on how, when or how much SUD information the non-part 2 provider can document within its own record, even when that information is transcribed from a received record from a part 2 program. This commenter stated that the preamble implies that, in order for part 2 not to apply, the non-part 2 provider needs to document the SUD information as part of a direct clinical patient encounter and upon reviewing it with the patient first, as opposed to directly copying from a record received from a part 2 program. The commenter stated that for appropriate care, non-part 2 providers should be able to document SUD information for safe patient care without the information becoming subject to 42 CFR part 2, regardless of how a part 2 program originally provides the information, or whether information is independently discussed with the patient during a visit.

SAMHSA Response

SAMHSA believes that the revisions to §§ 2.11 and 2.12 offer the appropriate fix for allowing a limited transfer of information between part 2 programs and non-part 2 providers, subject to patient consent, in order to facilitate better coordination of care. As discussed below, SAMHSA is also modifying the regulatory text in § 2.33(b), to add disclosures for the purpose of care coordination and case management to the list of permitted activities. Other forms of communication between lawful holders of part 2 records are also permitted under the part 2 regulations with patient consent, consistent with the enabling statute. The revisions to §§ 2.11 and 2.12 reflect a balance of interests between ensuring robust privacy protection for part 2 program treatment records, while also pursuing patient safety, reduction of adverse events, and better coordination of care for persons with SUD. SAMHSA will continue to consider opportunities for further re-alignment of part 2 requirements for the disclosure of SUD records for treatment, payment and health care operations in the future, to the extent permissible under the part 2 enabling statute and consistent with § 3221 of the CARES Act.

Public Comments

One commenter asked if the process of using the capabilities of certified electronic health record technology (CEHRT) to electronically ''copy'' a medication item, a problem or a medication allergy from the received part 2 document as an external list to the internal list maintained by the non-part 2 provider's CEHRT is considered ''transcription.'' This commenter asked that we include an example discussing a form of transcription that is permitted that does not violate the handling of a part 2 record received by a non-part 2 provider.

Likewise, another commenter specifically recommended that we revise the proposed regulations to allow health systems/providers using an integrated EHR to include the following in the patient's EHR without the patient's consent: Part 2 SUD in the integrated common problem list; Part 2 SUD treatment/post treatment medications on the integrated common medications list; medication allergies found during Part 2 SUD treatment/post treatment encounters on the integrated common medication allergy list; and an exception to obtaining a patient's consent to share this information for health systems/providers who use an integrated EHR.

SAMHSA Response

Currently, a part 2 program may make a disclosure with the patient's consent to a non-part 2 provider. Taken together, the effect of the revisions to §§ 2.11 and 2.12 is to clarify that the non-part 2 provider can then discuss that information in her own encounter with the patient, and create her own patient record that includes SUD information which will not be subject to part 2. The recipient non-part 2 provider is permitted but not required to segregate the received part 2 record (in whatever medium is relevant), as a way to ensure that her own subsequent record-keeping activity can be distinguished. These general principles continue to apply, regardless of whether the recipient non-part 2 provider is using a CEHRT [certified electronic health record technology]or whether the recipient non-part 2 provider and the part 2 program exchange their communications through a common, integrated EHR platform.

SAMHSA believes that revised §§ 2.11 and 2.12 strike the right balance of interests between ensuring robust privacy protection for part 2 program

treatment records, while also promoting patient safety, reduction of adverse events, and better coordination of care for persons with SUD. SAMHSA will continue to consider future guidance and refinement to the part 2 rules, and will continue to work with ONC to support and implement health IT policies consistent with the part 2 rules.

Public Comments

Many commenters asked for further clarification from SAMHSA in determining which records and providers are subject to part 2 requirements. Commenters specifically asked for definitions as to what ''holding oneself out as providing'' entails. Other commenters noted that, in the current healthcare environment and its emphasis on integrated care, providers are likely to apply the Part 2 requirements to more treatment settings and providers than required, creating excess compliance burden. Some commenters also noted that it is hard to imagine a scenario in which part 2 would prevent a specialist for any other chronic disease from supporting a treatment team without subjecting the entire team to unwieldy regulations. Commenters also stated that further clarification of the definition of a part 2 program could help patients choose which type of providers—and, consequently, confidentiality protections—they should seek.

One commenter recommended that SAMHSA clarify that Medication-Assisted Treatment (MAT) services and their associated workflows provided as part of a general medical facility do not meet the definition of a part 2 program, as long as the providers rendering the MAT services do not do so as their primary function within the facility. This commenter also recommended that SAMHSA clarify that any education or outreach (including posting notices, advertising and informing patients) about the availability of MAT services at a general medical facility, including Indian Health Service (IHS) and tribal facilities, would not change its status as a non-part 2 provider.

SAMHSA Response

SAMHSA appreciates these comments. Although outside the scope of the current rulemaking, SAMHSA will consider issuing guidance in the future to further clarify when a general medical facility is subject to the part 2 regulations.

Public Comments

A few commenters asked us to provide further guidance to clarify how health plans may similarly communicate with non-part 2 providers without subjecting their own records to part 2. Commenters asked if the proposed change applies to other lawful holders, specifically health plans.

SAMHSA Response

The revisions in § 2.12 establish that SUD treatment records created by a non-part 2 provider will not be covered by part 2, unless any SUD record previously received from a part 2 program is incorporated into such records. Under § 2.12, segregation of the received record can be used by non-part 2 providers to ensure that their own created patient records can be distinguished from the received record, and thus will not become covered by part 2.

The revisions in § 2.12 do not address the direct disclosure made by a health plan to a non-part 2 provider. In general, the broader part 2 framework concerning disclosures made by health plans as ''lawful holders'' continue to apply. SAMHSA will consider issuing future guidance to clarify the application of part 2 to disclosures of SUD records by health plans.

Public Comments

One commenter suggested that rather than modifying § 2.12 in order to facilitate disclosures by part 2 programs to non-part 2 providers in support of care coordination, it would instead be more effective under § 2.33 to add care coordination to the list of payment and operations activities for which a disclosure may be made with patient consent.

SAMHSA Response

SAMHSA believes that the current revisions to § 2.12 create an appropriate and limited pathway for part 2 programs to disclose SUD records to non-part 2 providers, and then to allow non-part 2 providers to create their own treatment records based on subsequent clinical encounters with their patients. However, as we explain below under § 2.33, SAMHSA has decided to modify the regulatory text in § 2.33(b), by adding disclosures for the purpose of care coordination and case management to the list of permitted activities under that section.

Public Comments

One commenter specifically recommended that SAMHSA clarify that systems that permit secure communication between patients, their permitted designates and non-part 2 caregivers may be used by part 2 caregivers that are employed by the same healthcare organization, or that use the same implementation of the secure communications system. This commenter also asked us to exempt communications between part 2 providers and non-part 2 healthcare providers that are actively engaged in the care of the same patient, but are not employed by the same healthcare organization. This commenter also asked that we specify that part 2 providers performing hospital consultation work may communicate with non-part 2 providers within the same organization without generating a part 2 covered record.

SAMHSA Response

Communications between patients, part 2 programs, and non-part 2 providers through patient portals and integrated EHR platforms can present an array of challenges and scenarios for patient consent under part 2. The current rulemaking does not attempt to address or resolve all such situations, nor does it change the status quo of how part 2 applies in many such situations.

SAMHSA will consider future guidance with regard to the application of part 2 to integrated EHR platforms, and particularly within integrated healthcare systems that include both part 2 programs and non-part 2 providers within the same system.

Public Comments

One commenter noted that SAMHSA did not make any proposals related to ''Jessie's Law.'' The commenter explained that Jessie's Law requires HHS to develop best practices for prominently displaying information relating to a patient's history of substance use in his or her treatment records when the patient makes a request for such disclosure.

SAMHSA Response

We will continue to work within HHS to ensure that we are complying with any applicable legal requirements stemming from Jessie's Law.

Public Comments

Several commenters noted support for our description of segregating records, specifically appreciating that we did not impose any new requirement for data segmentation as a practice or establish new standards for EHR technology. Commenters stated that this segregation policy should be flexible to allow providers with different operational capabilities to implement the policy in the least burdensome way and to offer an opportunity for the health IT industry to continue to work with stakeholders in the development of standards to meet patient privacy

expectations. One commenter stated the proposal would not incur significant additional burden on vendors because segmenting part 2 data has become an industry norm with the implementation of the Data Segmentation for Privacy standard, as well as the recent FHIR implementation guide for Consent2Share.

SAMHSA Response

We thank the commenters for their support.

Public Comments

A few commenters expressed clinical concerns with segmenting records, stating that to do so erodes the reliability of those records to support the delivery of safe care and may discourage the use of EHRs for specific types of SUD information. One commenter noted that this concern is especially important because FDA medical device guidance requires visibility into how IT systems arrive at their recommendations, which may not be possible in a world of segmented data. One commenter cautioned us, for these reasons, to only use data segmentation and separation in a limited way.

SAMHSA Response

The revisions in § 2.12 do not impose any requirements for non-part 2 providers to segment their electronic health records. Neither do the current revisions in § 2.12 impose any standards for segmenting electronic health records more generally. We believe it is important that providers include clinically relevant information within their records, while still respecting confidentiality requirements.

SAMHSA is sensitive to concerns about segmentation standards for EHRs. However, SAMHSA is not introducing new segmentation requirements or standards under this rule-making.

Public Comments

Some commenters supported the policy of segregating records under § 2.12, but said it is not a practical or best solution to promote the effective handling of SUD information to permit treatment and care coordination, noting that that the proposed changes still do not allow the exchange of information for these purposes without the written consent of the patient. These commenters argued that the policy would be burdensome and costly, and, because of the multitude of different operational standards and capabilities, part 2 programs will find themselves in an economically burdensome and legally questionable position as legal holders of information disclosed to them by patients seeking care. A few of these commenters also noted, however, that these burdens could not be overcome without statutory changes.

SAMHSA Response

We appreciate these comments. The revised § 2.12 does continue to require patient consent for the disclosure of a patient SUD record by a part 2 program to a non-part 2 provider. The revised § 2.12 reflects a balance of interests between ensuring robust privacy protection for part 2 program treatment records, while also promoting patient safety, reducing adverse events, and facilitating better coordination of care for persons with SUD.

SAMHSA does not believe that the revised § 2.12 will place part 2 programs under any greater operational or legal burden than they currently face, with regard to making disclosures to non-part 2 providers. Meanwhile, it would go considerably beyond the current rulemaking, and the current authorizing statute, to permit the disclosure of a patient record by a part 2 program to a non-part 2 provider, without the consent of the patient, except as otherwise permitted under Part 2.

Public Comments

A few commenters asked us to clarify the scenario in which one entity has Part 2 and non-Part 2 providers utilizing the same EHR that automatically populates diagnosis and prescription information. Commenters requested SAMHSA expand its proposal to clarify that if a general medical facility includes both Part 2 and non-Part 2 providers, then basic information that prepopulates, such as diagnosis and prescription information, is not subject to Part 2 requirements. Commenters further explained that some providers are unable to segregate records with any degree of confidence in their current workflows, and noted that many health systems either use separate EHRs or consider all providers in the system Part 2 providers due to burden and cost, which makes the referral of SUD and non-SUD patients and their health records more complicated. Other commenters similarly noted that they must treat all possible Part 2 information as if it were subject to the rule, and that requiring segmentation of part 2-protected patient records to prevent unauthorized redisclosure may be strictly interpreted by the non-part 2 recipients, causing the information to be inaccessible for care coordination or other purposes beneficial for the patient.

SAMHSA Response

Taken together, the effect of the revisions to §§ 2.11 and 2.12 is to allow the part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2. The recipient non-part 2 provider is permitted, but not required, to segregate the received part 2 record (in whatever medium is relevant), as a way to ensure that her own subsequent record-keeping activity can be distinguished. These general principles continue to apply, regardless of whether the recipient non-part 2 provider and the part 2 program exchange their communications through a shared, integrated EHR platform.

SAMHSA believes that revised §§ 2.11 and 2.12 strike the right balance of interests between ensuring robust privacy protection for part 2 program treatment records, while also promoting patient safety, reduction of adverse events, and better coordination of care for persons with SUD. SAMHSA will consider future guidance with regard to the application of part 2 to integrated EHR platforms, and particularly within integrated healthcare systems that include both part 2 programs and non-part 2 providers within the same system.

Public Comments

One commenter specifically noted concerns for IHS or tribal facilities still using the full Resource and Patient Management System (RPMS) EHR system. This commenter stated that, while non-part 2 IHS or tribal facilities could segregate a paper record fairly easily, the RPMS system does not allow for the segregation of electronic records. For this reason, the commenter recommended that IHS and tribal facilities using RPMS be exempted as to compliance with part 2 until IHS modernizes its EHR system. This commenter also asked that SAMHSA conduct tribal consultation to negotiate with tribes on part 2 compliance as to IHS and tribal facilities.

SAMHSA Response

It is beyond the scope of the current rulemaking for SAMHSA to address specific operational challenges for IHS or tribal facilities associated with part 2. SAMHSA notes, however, that there is no new requirement under § 2.12 for a non-part 2 provider to segregate any SUD records received from a part 2 program. There is also no requirement

under the revised § 2.12 for record-keeping practice at IHS or tribal facilities to change. Segregating a received part 2 record under § 2.12 is entirely at the option of the recipient provider.

Regardless, SAMHSA will consider conducting future tribal consultations and outreach around the revised part 2 rule, as an input to future guidance on implementation and compliance.

Public Comments

Several commenters stated what is meant by requiring the records to be ''segregated'' or ''segmented'' is unclear and unrealistic, and may mean creating an entirely separate EHR or resorting to paper medical records. One commenter suggested that SAMHSA should propose alternate solutions to segmentation by non-part 2 providers of records received from part 2 programs, which could ease provider burden. Commenters specifically noted concerns with technological barriers to segmenting non-Part 2 covered patient data, because current EHR technology does not allow for a provider to share just the non-Part 2 covered patient information with other providers, and asked SAMHSA to offer guidance. Commenters noted that, currently, there are no federal requirements for EHRs to include DS4P standards, and that, absent a requirement imposed on electronic medical record vendors to adopt DS4P and requirements for receiving providers to have a consent management system, this situation is unlikely to improve. Commenters also questioned whether it is feasible to require DS4P standards in all EHRs and urged SAMHSA to pursue additional testing of the DS4P standards and to work with developers and ONC on a solution. One commenter said that expecting programs to adopt compliant medical records could be expensive, disruptive to patient care, and problematic for many programs. As an alternative, this commenter suggested establishing minimum requirements for all EHRs through the appropriate EHR regulations.

SAMHSA Response

There is no requirement under revised § 2.12 for a non-part 2 provider to segregate or segment an SUD treatment record received from a part 2 program. It is beyond the scope of the current rulemaking to address a wide range of technical concerns about support for segmentation under specific EHR technologies; or concerns about the development or refinement of future DS4P standards; or concerns about the cost or burden to providers of adopting EHR systems in the future. None of these concerns detracts from the central premise of § 2.12, which is to establish that a patient record created by a non-part 2 provider will not become subject to part 2, simply because SUD information may be included within that record.

Nevertheless, SAMHSA remains broadly sensitive to concerns about segmentation, DS4P standards, and EHRs. SAMHSA will continue to collaborate with ONC and CMS on efforts that relate more directly to interoperability and standard-setting for EHRs.

Public Comments

Although some commenters appreciated that SAMHSA did not prescriptively state a requirement for use of the electronic data segmentation approaches, they similarly noted that DS4P and FHIR standards are still unsettled topics. Commenters explained that, while policies have been adopted and are being further proposed to ''tag'' sensitive health information in various ways, no progress has been made to provide support to identification of ''what'' is sensitive in a way that is semantically interoperable or at a meaningful level of data granularity. To make data segmentation a reality that is not burdensome, these commenters stated that many stakeholders must decide how sensitive health information can be ''tagged.'' Even with this consensus, some commenters expressed concern that tags are not persistent through transfer because DS4P does not detail how recipient systems should handle tagged data, and the scenarios under which it is appropriate to use/disclose data tagged as sensitive.

Commenters noted that these technical aspects will require a significant investment in time and resources to ensure the alignment of technical infrastructure and policy approaches for both EHRs and health information exchanges, requiring policy responses as well as the upgrade and maintenance of data dictionaries and technology components. Therefore, commenters urged SAMHSA to continue working with ONC on these issues. One commenter strongly urged SAMHSA to demonstrate commitment to greater interoperability and privacy protections by prioritizing data segmentation in development, testing, and policymaking, specifically noting the need for data segmentation to be made accessible and affordable to physicians.

SAMHSA Response

SAMHSA acknowledges that many technical issues and standards with regard to data segmentation and tagging practices remain unresolved, and are continuing to evolve rapidly. SAMHSA will monitor the field and continue to work with ONC on these issues, and will likewise collaborate with ONC and CMS on efforts that relate more directly to interoperability and standard-setting for EHRs. Regardless, SAMHSA continues to believe that EHRs that support tagging and segmentation offer one approach for implementing part 2 compliant clinical workflows.

Public Comments

A few commenters asked us to clarify if ''segregation'' or ''holding apart'' applies to claims data, which may hold information about a patient's diagnosis and treatment. One commenter asked that we work with ONC to clarify how treatment of SUD data by non-Part 2 providers will work under information blocking and TEFCA and administrative transaction policies.

SAMHSA Response

Under § 2.12, it is contemplated that a part 2 program may disclose a treatment record to a non-part 2 provider with the consent of the patient, in support of better coordination of care. In turn, the non-part 2 provider may then carry out her own clinical encounter with the patient, and create her own patient record that includes SUD information, without that record being subject to part 2. The non-part 2 provider may segregate any record previously received from the part 2 program as a way to distinguish this from her own clinical records. Note that all of the foregoing assumes an initial disclosure of a clinical record or information for treatment purposes, rather than a disclosure of claims data, by the part 2 program to the non-part 2 provider. A disclosure involving a claim would typically involve a health plan as a recipient, which is beyond the scope of the current revision of § 2.12 to address.

SAMHSA will continue to collaborate within the department on any potential future guidance as may involve health IT.

Public Comments

One commenter noted support of our proposal to clarify the language of § 2.12 from the use of ''any information'' to ''any records,'' and agrees that it better illustrates the intent SAMHSA describes in the preamble.

SAMHSA Response

We thank the commenter for its support.

Public Comments

One commenter asked for clarification on whether there is a distinction (or conversely, an ambiguity) between what constitutes the legally recognized medical record, versus shared information that is structured and record-like. In other words, at what threshold of structure and formality of conveyance does ''information'' become ''record?''

SAMHSA Response

SAMHSA does not draw any distinction between ''records'' as defined under § 2.11, versus ''shared information that is structured and record-like.'' Per the regulatory text of § 2.11, a ''record'' is defined as ''any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient.''

D. Consent Requirements (§ 2.31)

SAMHSA is finalizing this section as proposed, and adding further guidance concerning the application of § 2.31 to disclosures for the coordination of care, as outlined below.

In the 2017 final rule, SAMHSA made several changes to the consent requirements at § 2.31, to facilitate the sharing of information within the health care context, while ensuring the patient is fully informed and the necessary confidentiality protections are in place. Among those changes, SAMHSA amended the written consent requirements regarding identification of the individuals and entities to whom disclosures of protected information may be made (82 FR 6077). Specifically, SAMHSA adopted a framework for disclosures to entities that made several distinctions between recipients that have a treating provider relationship with the patient and recipients that do not. Under the current rules at § 2.31(a)(4), if the recipient entity does not have a treating provider relationship with the patient whose information is being disclosed and is not a third-party payer, such as an entity that facilitates the exchange of health care information or research institutions, the written consent must include the name of the entity and one of the following: *The name(s) of an individual participant(s); the name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or a general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed.* As stated in the 2017 final rule, SAMHSA wants to ensure that patient identifying information is only disclosed to those individuals and entities on the health care team with a need to know this sensitive information (82 FR 6084). SAMHSA, accordingly, limited the ability to use a general designation in the 'to whom' section of the consent requirements to those individuals or entities with a treating provider relationship to the patient at issue.

Since the 2017 final rule was published, SAMHSA has learned that some patients with SUDs would like part 2 programs to disclose their protected information to entities for reasons including eligibility determinations and seeking non-medical services or benefits from governmental and non-governmental entities (*e.g.,* social security benefits, local sober living or halfway house programs). Because these entities lack a treating provider relationship with the patient, the current rules preclude them from being designated by name to receive the information, unless they are third-party payers, or the patient knows the identity of the specific individual who would receive the information on behalf of the benefit program or service provider. In addition, many of these entities may not be able to identify a specific employee to receive application information, and instead are likely to encourage patients to contact them or apply online, such that information is submitted to the organization rather than to a specific person. SAMHSA has heard that many patients have encountered frustration and delays in applying for and receiving services and benefits from, and in authorizing part 2 providers to release their information to, entities providing such services and benefits, by virtue of the inability to designate these entities by organization name only on the written consent for disclosure of part 2 information.

We also understand that the requirement to include an individual's name could make it more burdensome for part 2 programs or lawful holders to facilitate a patient's specific consent to share their information with a contractor or subcontractor that performs care coordination or case management activities on behalf of the program or lawful holder. It is not SAMHSA's intent to limit patients' ability to consent to the disclosure of their own information or create barriers to care coordination. We wish, rather, to empower patients to consent to the release and use of their health information in whatever way they choose, consistent with statutory and regulatory protections designed to ensure the integrity of the consent process.

Therefore, in this final rule, SAMHSA is amending the current regulations to clarify when patients may consent to disclosures of part 2 information to organizations without a treating provider relationship. In particular, SAMHSA has amended § 2.31(a)(4)(i), which previously required a written consent to include the names of individual(s) to whom a disclosure is to be made. The amended section inserts the words ''or the name(s) of the entity(-ies)'' to that section, so that a written consent must include the name(s) of the individual(s) or entity(-ies) to whom or to which a disclosure is to be made. SAMHSA believes that this language aligns more closely with the wording of the regulation before the January 2017 final rule changes, and would alleviate problems caused by the inability to designate by name an individual recipient at an entity. For example, if a patient wants a part 2 program to disclose impairment information to the Social Security Administration for a determination of benefits, such patient would only need to authorize this agency on the ''to whom'' section of the consent form, rather than identify a specific individual at the agency to receive such information. In addition, in response to the many comments requesting that SAMHSA provide more flexibility throughout the rule to facilitate care coordination and case management, the change at § 42 CFR 2.31(a)(4)(i) will also make it easier for patients to consent to the disclosure of their information for the purposes of care coordination and case management, including to contracted organizations of lawful holders, by naming such organizations on the consent form.

SAMHSA has removed old § 2.31(a)(4)(ii) and (iii)(A), and redesignated old § 2.31(a)(4)(iii)(B) as § 2.31(a)(4)(ii) in the final rule. SAMHSA has also amended the newly redesignated § 2.31(a)(4)(ii), so that it applies only to entities that facilitate the exchange of health information (*e.g.,* health information exchanges (HIEs)) or research institutions. The section establishes that, if the recipient entity is an entity that facilitates the exchange of health information or is a research institution, the consent must include the name of the entity and one of the following: (1) The name(s) of an individual or entity participant(s); or (2) a general designation of an individual or entity participant(s) or class of participants, limited to a participant(s)

who has a treating provider relationship with the patient whose information is being disclosed. We have also made conforming amendments to §§ 2.12(d)(2)(a) and 2.13(d). The revised language of 2.31(a)(4) does continue to permit patient consent to disclosures to third-party payers based on naming the recipient entity, without specifying an individual recipient at that entity.

The comments we received on this proposal and our responses are provided below.

Public Comments

Many commenters supported our proposal to allow patients to consent to disclosure to entities without a treating provider relationship without naming the specific individual receiving the information. These commenters stated that this proposal would break down barriers for patients and remove delays in seeking and receiving often life-saving services or benefits from entities, allowing integrated information exchange between all necessary services, including collaborative non-treatment services related to substance use. Commenters believed that this proposal would empower patients to determine whether it is in their interest to share their own protected SUD information with health and social service entities, putting ''patients over paperwork.'' Commenters also noted that this proposed change would align with the modern innovations of complex, fluid teams that meet individual patient needs and ''whole person'' care models, many of which may address underlying social determinants that can affect a patient's health status. Commenters also noted the proposal would significantly enhance efforts at interoperability and getting information where and when it is needed at the point of care. Finally, commenters applauded this change because is more closely aligns with HIPAA standards.

SAMHSA Response

We thank the commenters for their support.

Public Comments

Several commenters opposed this proposal, fearing that information would be given to interconnected health care systems, unknown future entities, and vendors with one general consent and signature. One commenter asked that the consent continue to include the specific information to be shared, with whom specifically, and the time constraints of the release of information. A few commenters stated that the proposal raised trust, privacy, and confidentiality concerns and would deter treatment. One commenter asked that this consent be an ''option'' rather than ''preferred.''

SAMHSA Response

As noted above, SAMHSA has learned that some patients with SUDs may want part 2 programs to disclose protected information to entities for reasons including eligibility determinations and seeking nonmedical services or benefits from governmental and non-governmental entities (*e.g.,* social security benefits, local sober living or halfway house programs). However, the old rule precluded patients from designating an entity's name by itself on the consent form, unless the entity was a third-party payer. To alleviate frustration and delays in applying for and receiving services and benefits, SAMHSA amended the regulations to clarify that patients may consent to disclosures of part 2 information to organizations without a treating provider relationship. We note that § 2.31(a)(5) requires the consent form to include the purpose of the disclosure, which must be limited to that information which is necessary to carry out the stated purpose. Under § 2.31(a)(7), the consent form must include the date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided. We believe that these safeguards will alleviate any concerns that the consent may be too broad, while appropriately allowing the patient to choose to whom their records are disclosed.

Public Comments

Many commenters asked us to further expand the proposal to allow broader consent. A few commenters recommended that we make additional revisions which would permit generalized consents, authorizing both disclosures and re-disclosures of Part 2 records for treatment, payment, and health care operations (TPO) purposes among HIPAA ''covered entities,'' Part 2 programs, and HIPAA ''business associates'' to receive their full medical records, noting this global consent would result in better care coordination and avoid delays. Another commenter recommended adding regulatory language to specify that patients may consent to permit both their Part 2 facility and health information exchange networks of their choosing to disclose their health information to past, present, and future treating providers. Another commenter requested that we allow consent for information to be disclosed to categories or types of organizations. Similarly, a few commenters requested that we clarify that organizations like accountable care organizations and health homes can be considered to have a ''treating provider relationship'' with a patient. Likewise, a few commenters asked us to clarify whether the proposed changes apply to entities that receive information from Part 2 providers for non-treatment purposes such as health plans, business associates, healthcare clearinghouses, and third-party payers. These commenters claimed that there is little to no legal distinction between broadening the To Whom requirement for non-treatment and treatment purposes under Part 2, and that broadening in this way could help to streamline Part 2 and HIPAA.

SAMHSA Response

As noted above, under § 2.31, patients control to whom and for what purposes they consent to disclosure of information. Under this proposal, SAMHSA is amending the regulations to clarify that patients may consent to disclosures of part 2 information to organizations without a treating provider relationship. We believe that this policy appropriately balances patients' empowerment with confidentiality concerns.

However, the change we are making will make it easier for patients to consent to share their records for the purposes of care coordination and case management. Patients may consent to share their information with a contractor or subcontractor that performs care coordination or case management on behalf of a part 2 program or lawful holder, if the consent form specifies the contracted organization name in the ''to whom'' section, describes the specific types of activities to be undertaken in the ''purpose'' section; and meets all other required elements outlined in § 2.31. Similarly, a patient may consent to share their records for the purpose of care coordination with his or her treating provider organization or health insurer, if the provider organization or health plan is named in the ''to whom'' section and the specific types of care coordination or case management activities are described in the purpose section of the consent form.

SAMHSA will consider making further revisions to the consent requirements under § 2.31 in the future, particularly as needed to implement § 3221 of the CARES Act.

Public Comments

One commenter requested clarification regarding the proposed changes to § 2.31 (a)(4)(ii)(B), specifically asking about a scenario in which a part 2 program includes a statement on a consent form to share part 2 information with a PDMP, and must, upon request, provide the patient with a list of entities to which their information has been disclosed pursuant to the general designation in § 2.13(d). The commenter inquired about the level of specificity that is required for the ''list of entities.'' This commenter noted that a state may only have the ability to disclose that a patient's information was accessed by another state's PDMP, but may not have access to the records for individual end-users in that state's PDMP.

SAMHSA Response

Under § 2.36, disclosures to PDMPs will be accomplished by direct consent and not using a general designation to which the List of Disclosures requirement in § 2.13(d) applies. As a result, a patient would not be able to request a list of entities under § 2.13(d) to which the PDMP made disclosures.

Public Comments

One commenter argued that there should be an option for a ''general designation'' that encompasses all providers within an organization, not just those who already have a treatment relationship with the patient. This commenter asked that we add the following language to the regulation: ''A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed or who has in place a written contract or comparable legal instrument with the individual or entity that requires the participant(s) to be fully bound by the provisions of Part 2 upon receipt of patient identifying information.''

SAMHSA Response

As stated in the January 2017 final rule (82 FR 6084), for entities that facilitate the exchange of health information or are research institutions, SAMHSA wants to ensure that patient identifying information is only disclosed to those individuals and entities on the health care team with a need to know this sensitive information. Therefore, in instances where information is disclosed to entities that facilitate the exchange of health information or research institutions, SAMHSA will continue to limit the ability to use a general designation (*e.g.,* ''all my treating providers'') in the ''to whom'' section of the consent requirements to those individuals or entities with a treating provider relationship.

Public Comments

A few commenters supported our proposal, but asked us to provide additional examples and definitions of ''entity'' in the final rule. Commenters noted that this clarification would help providers comply with the provision. One commenter asked that we clarify the applicability of § 2.31(a)(4)(i) to third-party administrators and/or representatives that operate on behalf of a governmental and/or nongovernmental entity. The commenter also asked us to clarify under the proposed rule the applicability of § 2.31(a)(4)(i) in instances in which the requirements of § 2.15(a)(1) have been met and a patient's guardian or personal representative authorized under state law may act on behalf of the patient. A few commenters asked us to carefully define ''entity'' to specify an individual or entity that has a direct treating provider or clinical relationship with the patient.

SAMHSA Response

SAMHSA is amending § 2.31 to enable patients to broadly consent to disclose their records to any entity of their choosing, without naming an individual recipient within such entity. A patient may choose to disclose their records to an entity with which they do not have a treating provider relationship, except in situations where a general designation is used to disclose information to entities that facilitate the exchange of health information or to research institutions. In that case, a general designation of an individual or entity participant(s) or class of participants must be limited to a participant(s) with a treating provider relationship with the patient whose information is being disclosed. Given our desire to ensure patients may consent to any entity or its representatives as they so choose, SAMHSA does not believe that further defining the term ''entity'' is necessary. Section 2.15(a) states that in the case where a patient has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage their own affairs, any consent that is required under the regulations in this part may be given by the guardian or other individual authorized under state law to act in the patient's behalf.

Public Comments

A few commenters asked us to include anti-discrimination protections in the regulations that forbid the use of any information disclosed for the purposes of limiting access to health, life, or disability insurance coverage; limiting access to protections under the ADA; limiting access to health care; criminal or civil investigation or prosecution; sharing information with the patient's employer; sharing information with child welfare agencies or family courts; or limiting or denying the patient's rights or benefits in any way.

SAMHSA Response

As we have previously indicated, promulgating rules that address discriminatory action is outside the scope of SAMHSA's current legal authority (see 83 FR 248). However, we refer the commenter to § 2.13(a), which states that patient records subject to the Part 2 regulations may be disclosed or used only as permitted by the regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Further, §§ 2.64 and 2.65 describe required procedures and criteria for orders authorizing disclosures for criminal investigations of patients and for non-criminal purposes (such as a civil action), which provide safeguards for patients. Finally, we note that § 3221(g) of the CARES Act does include antidiscrimination language, and we anticipate implementing that provision in future rulemaking.

Public Comments

One commenter requested clarification as to how the proposal would apply to a medical entity such as a clinic. The commenter asked if all providers dealing with the patient in a clinic would have access to the disclosed information. The commenter stated that it is their understanding that some treatment records can be marked as confidential in certain electronic health records, but that medications and diagnoses typically are not.

SAMHSA Response

Although SAMHSA has amended the current regulations to clarify that a patient may consent to the disclosure of part 2 information to an entity without naming a specific individual as the recipient, current rules already allow consent to an entity with a treating provider relationship, and this consent flows to entity staff with a need to access the Part 2-covered information.

We note that § 2.31(a)(5) of the regulations continues to require the consent form to include the purpose of the disclosure. The disclosure of patient identifying information must be limited to that information which is necessary to carry out the stated purpose. Thus, a clinic receiving the disclosed information may only share the patient's information in order to meet the purpose of the disclosure as described on the consent form.

Public Comments

One commenter recommended that a tribally operated or American Indian part 2 program be authorized to share a patient's SUD treatment information with IHS, tribal, or urban Indian health primary care providers for treatment purposes without patient consent, stating that this change is needed to facilitate care within the Indian health system.

SAMHSA Response

We appreciate the comment and concern for ensuring patients within the Indian Health Service receive effective care. SAMHSA does not have the authority to exempt patients within the IHS from the part 2 consent requirements. However, we note that the changes we are finalizing in this final rule to promote care coordination between part 2 programs and primary care doctors would similarly apply to IHS providers and patients.

Public Comments

One commenter asked us to develop template consent forms that meet the requirements of the final rules for ease and convenience of patients and providers.

SAMHSA Response

We thank the commenter for the suggestion and will consider issuing guidance related to the consent form requirements in the future.

Public Comments

A few commenters asked that we allow for an ''opt-out'' consent process similar to that under HIPAA, in which patient information would be permitted to be used and disclosed for treatment, payment, and health care operations unless the patient opts-out.

SAMHSA Response

The authorizing statute for the part 2 rules expressly requires written consent for most uses and disclosures of SUD patient records. We believe that this policy appropriately balances patients' empowerment with confidentiality concerns. We further note, however, that § 3221 of the CARES Act contemplates modifying the parameters for consent to the disclosure of a patient record for the purpose of treatment, payment and health care operations. We anticipate making further revisions to part 2 in the future, in order to implement the relevant provisions of the CARES Act.

Public Comments

One commenter encouraged us to expand the list of safe harbors for those acting in good faith who are trying to help an individual obtain housing, health care, or other necessary services. The commenter also asked us to align with the HHS Office for Civil Rights (OCR) on future regulations and guidance specifically discussing these scenarios and the ability to share health information for critical individual needs.

SAMHSA Response

We thank the commenter for the suggestions and will consider them in the future.

Public Comment

One commenter requested clarification on how patient confidentiality will be assured under this proposal.

SAMHSA Response

As noted above, records are only disclosed at the patient's request and after consent under this section; therefore, the patient remains in control of his/her records and with whom and for what purposes these records are shared. Records disclosed under this section will retain their status as protected part 2 records in the hands of downstream recipients. We refer the commenter to § 2.32, which describes the notice that must be provided to recipients of part 2 records disclosed under § 2.31. The notice prohibits redisclosure of the records unless expressly permitted by the written consent of the individual whose information is being disclosed or, otherwise permitted by 42 CFR part 2.

Public Comments

One commenter stated that the rule change needed to be clarified across the regulation to ensure that individuals do not need to be listed to consent to an entity.

SAMHSA Response

SAMHSA believes that clarifying this change in the regulatory text of § 2.31 is sufficient to ensure that individuals do not need to be listed when a patient consents to sharing his or her records with an entity.

Public Comments

One commenter, although supporting our proposal, noted the importance of the safeguards inherent in the general designation that allow the individual to request a list of entities to which their information has been disclosed.

SAMHSA Response

We appreciate feedback regarding the importance of safeguards that allow an individual to request a list of entities to which their information has been disclosed under the general designation option.

Public Comments

A few commenters requested that we allow individuals to consent to disclosure to entities without listing an individual as the recipient, in instances where information is disclosed to entities that facilitate the exchange of health information or research institutions. These commenters stated that patients are not aware of the information sharing happening at the provider level by Health Information Networks (HINs) and HIEs, most of which is done to coordinate care and benefit a patient's care. Without this change, commenters said that Part 2 information sharing that is happening at the HIN and HIE level could be halted, and burden to providers may increase. Commenters also argued that this change is also not legally different than adopting the same position with respect to treatment purposes and this change would align with the CMS and ONC interoperability goals.

SAMHSA Response

Newly finalized language in § 2.31(a)(4)(ii) continues to allow patients to use a general designation in consenting to disclose their records to organizations that facilitate the exchange of health information. Specifically, if a recipient entity facilitates the exchange of health information or is a research institution, a written consent must include the name(s) of the entity and either the name of the individual or entity participants, or a general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed (*e.g.,* ''my treating providers'').

Public Comments

One commenter noted that SAMHSA did not provide a definition in the

proposed rule on what constitutes an HIE, and asked us to define what types of organizations qualify as HIEs.

SAMHSA Response

On May 1, 2020, ONC published its final rule on interoperability under the 21st Century Cures Act (85 FR 25642). As a part of the final interoperability rule, ONC did provide a definition for what constitutes an HIE (to be codified at 45 CFR 171.102). SAMHSA is hereby incorporating that definition by reference, for the purpose of this rule.

Public Comments

One commenter noted the tension between the functionality of an HIE and protecting patient privacy. This commenter encouraged us to carefully explore the relationship between part 2 data and HIEs in future guidance, in order to identify solutions that can allow for rapid data transfer while protecting patient privacy.

SAMHSA Response

We thank the commenter for this suggestion and will consider issuing additional guidance related to HIEs in the future. SAMHSA will also consider other educational activities, such as trainings and webinars, should SAMHSA determine the need during implementation of the final rule.

Public Comments

One commenter noted that the exclusion of HIEs is overbroad, stating that if SAMHSA wants to ensure that organizations that access a patient's information under a general designation only do so for purposes of caring for the patient, it could adopt a provision that simply says an HIE can only use a general designation on its consent form if it has policies to ensure that participants obtain information under the general designation only for limited purposes, such as treatment, payment, or health care operations as defined under HIPAA.

SAMHSA Response

At this time, we do not believe this exclusion to be overbroad. As stated above, newly finalized language in § 2.31(a)(4)(ii) continues to allow patients to use a general designation in consenting to disclose their records to organizations that facilitate the exchange of health information. Specifically, if a recipient entity facilitates the exchange of health information or is a research institution, a written consent must include the name(s) of the entity and either the name of the individual or entity participants, or a general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed (*e.g.,* ''my treating providers''). We will, however, consider this suggestion in the future if we find the current language to be limiting to patients.

E. Prohibition on Re-Disclosure (§ 2.32)

SAMHSA is finalizing this section as proposed.

In the 2017 final rule, SAMHSA clarified that the disclosure restrictions on SUD patient records would extend to individuals or entities who receive such records either from a part 2 program or from another lawful holder. We further emphasized this clarification in the notice requirements in § 2.32 in the 2017 final rule. Under § 2.32, each disclosure made with a patient's consent must contain a written statement notifying the recipient of the applicability of 42 CFR part 2 to any re-disclosure of the protected record. In the 2017 final rule, SAMHSA noted that the prohibition on redisclosure provision only applied to information from the record that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a SUD by a part 2-covered provider. The prohibition still allowed other health-related information shared by the part 2 program to be re-disclosed, if permissible under the applicable law (82 FR 6089).

SAMHSA has since heard from the provider community that this section of the regulation prompted downstream, non-part 2 providers to manually redact portions of their disclosure data files that identify a patient as having or having had a SUD. This activity is operationally burdensome and not the intent of the 2017 final rule. As noted in Section IV.C. above, SAMHSA has proposed to modify § 2.12 to clarify that the recording of information about an SUD and its treatment by a non-part 2 provider is permitted and not subject to part 2, and that the non-part 2 provider may segregate or segment any patient record previously received from a part 2 program to ensure that she can distinguish them from her own patient records created following clinical encounters. Therefore, a downstream non-part 2 provider would not need to redact SUD information in its own records in an effort to comply with part 2, provided that any outside patient record previously received from a part 2 program or other lawful holder is segregated or segmented.

To ensure that downstream non-part 2 providers are aware that they do not need to redact information in their files if they have means of identifying the part 2-covered data (*e.g.,* by segregating or segmenting the files received from the part 2 program), SAMHSA proposed to modify and streamline the notice language in § 2.32(a)(1) to remove the superfluous language that has contributed to confusion regarding the restrictions on re-disclosures (84 FR 44574). Specifically, we proposed to remove ''information in'' and ''that identifies a patient as having or having had a SUD either directly, by reference to publicly available information, or through verification of such identification by another person,'' from the current notice language established in the regulation. Additionally, SAMHSA added language to specifically state that only the part 2 record is subject to the prohibition on re-disclosure in § 2.32, unless further disclosure either is expressly permitted by written consent of the individual whose information is being disclosed in the record or is otherwise permitted by 42 CFR part 2 (84 FR 44574).

The comments we received on the proposed amendments to § 2.32 and our responses are provided below.

Public Comments

Several commenters supported our proposal to streamline the redisclosure language in § 2.32, stating that the change would reduce counterproductive provider burden, decrease confusion, and would also support enhanced, whole-person care coordination for the benefit of the patient. One commenter specifically noted that because of the way the provision was previously worded, providers would redact critical patient information for fear of violating Part 2, leading to gaps in care. One commenter, while supporting the proposal, noted that the need to revise this language may be limited, because of the ability to use an alternative short form of the notice which was implemented in the 2018 final rule. Some commenters, while supporting the proposal, requested additional clarification on how patient confidentiality will be assured.

SAMHSA Response

We thank the commenters for their support. As noted above, part 2 records will continue to be protected by part 2: The changes in § 2.32 of the final rule merely provide clarity so that non-part 2 providers will better understand that they do not need to redact patient information from their own clinical records that are not protected by part 2.

Thus, we believe that patient confidentiality will still be appropriately maintained under this proposal.

Public Comments

Some commenters opposed our proposal to streamline the redisclosure language in § 2.32, noting confidentiality concerns and potential negative impacts to clinical decision-making. One commenter specifically stated that patients would be reluctant to sign a consent for disclosure of their records for legitimate reasons, knowing that once the medical records are sent out, they can be disseminated without the patient's consent.

SAMHSA Response

SAMHSA does not believe that the final rule on § 2.32 changes the basic consent requirements in the regulations. Instead, as stated above, the change in § 2.32 simply streamlines the required ''Notice'' language, to ensure that non-part 2 providers are not burdensomely seeking to redact large amounts of text from a patient's general medical record that is not protected under Part 2. In addition, SAMHSA does not anticipate any adverse impact from the final rule on § 2.32 on clinical decision making. In fact, the more information received by a downstream clinician in a record that is not redacted, the better informed that clinician will be, thereby facilitating better informed patient-clinician decisions.

Public Comments

A few commenters specifically stated that they did not support this proposal because of the corresponding changes being proposed to § 2.11. These commenters asserted that information conveyed from a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient would no longer be protected by the Part 2 rules and only subject to HIPAA, which has fewer protections and could lead to medical care discrimination and increased legal prosecution.

SAMHSA Response

As stated above, under this rule, any record disclosed by a part 2 program to a non-part 2 provider will still be subject to part 2, and the recipient's own clinical record might also become subject to part 2 if the received record is wholly incorporated into the non-part 2 provider's own patient record. Thus, § 2.33 would continue to apply to records in these instances.

Public Comments

A few commenters, although supporting the intent of the proposal, noted difficulties in operationalizing the provision with EHRs. These commenters recommended that future regulations clarify the re-disclosure requirements, and recognize the existing challenges within both paper and electronic environments. The commenters encouraged SAMHSA to provide better examples and guidance for successfully implementing the redisclosure requirements. One commenter specifically asked SAMHSA to engage in pilot testing and evaluation of relevant standards and technologies and suggested establishing a temporary safe harbor for enforcement while the technical issues are studied. This commenter also asked that, given the difficulty of distinguishing part 2 records from general medical information, SAMHSA consider lesser penalties for ''good faith'' errors in contrast to malicious or other intentionally wrongful disclosures.

SAMHSA Response

In the 2018 final rule, SAMHSA explicitly adopted an abbreviated notice that is 80 characters long to fit in standard free-text space within health care electronic systems (83 FR 240). SAMHSA has not proposed any change to this abbreviated notice language in § 2.32; thus, stakeholders may continue using this language in their EHR systems. As we previously noted in the 2018 final rule, SAMHSA acknowledges that there may be technical issues connected to compliance with § 2.32 which will require future guidance to resolve. Nevertheless, SAMHSA believes that the current final rule on § 2.32 involves an appropriate balance of interests at present. SAMHSA will continue to work with stakeholders, as needed, to provide guidance in the future.

Public Comments

One commenter stated that the proposal will need to be enforced to be effective, citing examples of third parties re-disclosing records, even though all the pages are stamped with the non-re disclosure statement.

SAMHSA Response

We also believe enforcing part 2 is important to protect confidentiality of patients. We will continue to pursue enforcement of this and other provisions under part 2.

Public Comments

A few commenters asked us to take the proposal further, by completely eliminating the redisclosure prohibition, stating that the statute does not require it. Commenters noted that downstream redisclosures would fall under HIPAA protections, which are robust in nature and familiar to those entities and individuals who would be engaging in the redisclosures.

SAMHSA Response

As stated in the 2017 final rule, while the statute may not be explicit with regard to all provisions in 42 CFR part 2, the statute directs the Secretary to provide for such safeguards and procedures as, in the judgment of the Secretary, are necessary or proper to effectuate the purposes of this statute, to prevent circumvention or evasion thereof, or to facilitate compliance therewith (82 FR 6089). At this time, SAMHSA believes that § 2.32 is still necessary, on balance, to appropriately protect the confidentiality of patients.

We do anticipate making further revisions to part 2 in the future, in order to implement the relevant provisions of the CARES Act, and we will review the status of § 2.32 in any future rulemaking.

Public Comments

One commenter recommended that SAMHSA add notice language to § 2.32, to reinforce that the non-part 2 provider/entity has received the part 2-protected SUD information for the permissible purpose of improving service delivery for the patient, and that although unauthorized redisclosure of part 2-protected information is prohibited, this information should be used as intended for the permissible purpose.

SAMHSA Response

The final rule at § 2.32 does not specify particular purposes for which part 2 protected records must be used, once the patient consents to such use. We believe it is best to empower patients to specify the terms for a limited disclosure, rather than adding compulsory requirements for the use of disclosed records, which might be confusing and could cause providers to limit the disclosure of important information intended to be conveyed by the patient.

F. Disclosures Permitted With Written Consent (§ 2.33)

In response to comments received on the proposed rule and the CARES Act provision incorporating into 42 U.S.C. 290dd–2 the HIPAA Privacy Rule definition of health care operations, which includes care coordination and case management activities, SAMHSA is

modifying this section of the rule from what was proposed, to add care coordination and case management as an example of an activity for which a lawful holder may make a further disclosure to its contractors, subcontractors and/or legal representatives, in support of health care payment or operations. In order to avoid confusion about the extent of § 2.33(b), SAMHSA has also deleted from the regulatory text the statement that ''Disclosures to contractors, subcontractors, and legal representatives to carry out other purposes such as substance use disorder patient diagnosis, treatment, or referral for treatment are not permitted under this section.''

While we did not specifically propose to include care coordination and case management in the list of activities under § 2.33(b), the NPRM addressed the issue of how to facilitate these types of services, and we received public comments on this point. More recently, Congress passed the CARES Act, which expressly permits disclosure of Part 2 information for these very purposes. To the extent that there may be a concern that we did not formally and specifically solicit public comment on listing care coordination and case management in § 2.33(b), we believe that further notice and comment on this matter is unnecessary. The Department's statements in the NPRM elicited comments on this issue, and the subsequent passage of the CARES Act would otherwise effectuate § 2.33(b) of this final rule starting March 27, 2021. Additionally, permitting disclosures under § 2.33(b) for case management and care coordination services in this final rule will have the effect of granting providers, part 2 programs and lawful holders more time in which to establish processes for carrying out these essential services in accordance with the requirements of this final rule and the CARES Act provisions. Therefore, the Department finds good cause to forego notice and comment on whether care coordination and case management activities should be included in the illustrative list of permissible payment and health care operations activities under 2.33(b). 5 U.S.C. 553(b)(B)(an agency is exempt from the notice and comment requirements of the Administrative Procedure Act if the agency ''for good cause finds . . . notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest'').

In the 2018 final rule (83 FR 241), SAMHSA clarified at § 2.33(b), the scope and requirements for permitted disclosures by a lawful holder to contractors, subcontractors, and legal representatives, for the purpose of payment and certain health care operations. In the 2017 proposed rule, SAMHSA proposed to include in the regulatory text a list of 17 specific types of permitted categories of payment and health care operations (82 FR 5487).

Based on the numerous comments received requesting additions or clarifications to the list, as well as concerns that the changes occurring in the health care payment and delivery system could rapidly render any list of activities included in the regulatory text outdated, SAMHSA decided not to include the list of 17 activities in the regulation text in the 2018 final rule, and, instead, decided to include a list of the types of permitted activities in the preamble of the 2018 final rule. SAMHSA stated in the 2018 final rule that we included this list of activities in the preamble in order to make clear that it is an illustrative rather than exhaustive list of the types of payment and health care operations activities that would be acceptable to SAMHSA (83 FR 241). By removing the list from the regulatory text, SAMHSA intended for other appropriate payment and health care operations activities to be permitted under § 2.33 as the health care system continues to evolve.

Since the 2018 final rule was published, SAMHSA has learned that including an illustrative list of permissible activities in the preamble rather than in the text of the regulation did not fully clarify the circumstances under which part 2 information could be further disclosed under § 2.33. Specifically, stakeholders may have believed that a particular activity was not permissible unless explicitly identified within the regulatory text. Therefore, to clear up any remaining confusion, SAMHSA proposed to amend § 2.33(b) to expressly include the illustrative list of permissible activities that was contained in the preamble of the 2018 final rule (83 FR 243). It is important to note, as was noted in the preamble to the 2018 final rule, that this list is illustrative rather than exhaustive.

Specifically, SAMHSA proposed to add the following examples of permissible activities that SAMHSA considers to be payment and health care operations activities to § 2.33(b):

- Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing;
- Clinical professional support services (*e.g.,* quality assessment and improvement initiatives; utilization review and management services);
- Patient safety activities;
- Activities pertaining to:
  - The training of student trainees and health care professionals;
  - The assessment of practitioner competencies;
  - The assessment of provider and/or health plan performance; and/or
  - Training of non-health care professionals;
- Accreditation, certification, licensing, or credentialing activities;
- Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and/or ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;
- Third-party liability coverage;
- Activities related to addressing fraud, waste and/or abuse; Conducting or arranging for medical review, legal services, and/or auditing functions;
- Business planning and development, such as conducting cost management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies;
- Business management and/or general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations;
- Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;
- Resolution of internal grievances;
- The sale, transfer, merger, consolidation, or dissolution of an organization;
- Determinations of eligibility or coverage (*e.g.,* coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;
- Risk adjusting amounts due based on enrollee health status and demographic characteristics; and
- Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges.

To further clarify that the list is not exhaustive, SAMHSA also proposed to add ''other payment/health care operations activities not expressly prohibited'' in this provision to the end of the list. SAMHSA also again clarified in the preamble to the proposed rule (84 FR 44575) that § 2.33(b) was not intended to cover disclosures to contractors, subcontractors, and legal

representatives for the purposes of care coordination or case management, and disclosures to carry out such purposes were not permitted under this section. We noted that this policy differs from the HIPAA Privacy Rule, under which 'health care operations' encompasses such activities as case management and care coordination. SAMHSA previously emphasized the importance of maintaining patient choice in disclosing information to health care providers with whom they will have direct contact (83 FR 243). We stated in the proposed rule that although § 2.33(b) does not cover disclosures for the purpose of care coordination or case management, such disclosures may nevertheless be made under other provisions of §§ 2.31 and 2.33. Additionally, we noted that several of the proposals to revise other sections of part 2 in this rulemaking would help to facilitate coordination of care, as under § 2.12 (Applicability). However, as discussed above, due to recent CARES Act amendments as well as public comments, SAMHSA has decided to include care coordination and case management in the illustrative list of examples of payment and health care operations activities for which disclosures may be made under § 2.33(b).

At this time, we note that this rule provides transitional regulations until such time as implementing regulations for § 3221 of the CARES Act come into effect. In future rulemaking, we will consider further revisions to § 2.33, as needed to implement relevant provisions under the CARES Act.

The comments we received on the proposed amendments to § 2.33 and our responses are provided below.

Public Comments

Several commenters expressed support for the proposed changes, saying that moving the list to the regulatory text reduces confusion; appropriately acknowledges the modern health care landscape and the role of third-party entities in facilitating access to SUD treatment services; and provides a helpful guide as to what information may be shared and for what purposes. One commenter said that SAMHSA is trying to do what it can to enable appropriate disclosures for the sake of part 2 program operations and coordination of care and still reasonably protect the privacy of the part 2 patient. Another appreciated the addition of the 18th item, ''other payment/health care operations activities not expressly prohibited,'' to clarify that the list is not exhaustive. One commenter supported the changes but said that adding these fairly numerous exceptions will add greater complexity to a regulation with which providers and payers already struggle. Other commenters supported the change but requested that SAMHSA include care coordination and case management in the list of permitted activities, as discussed further below.

SAMHSA Response

We thank the commenters for their support and insights about the change. We address in a subsequent answer below public comments requesting the addition of care coordination and case management to the list of permitted activities in § 2.33(b).

Public Comments

One commenter supported the changes to § 2.33 but requested additional clarification on how patient confidentiality will be assured.

SAMHSA Response

We refer the commenter to § 2.33(c), which outlines contract provisions for disclosures made under § 2.33(b), ensuring that that contractors, subcontractors or voluntary legal representatives who receive information pursuant to this section are fully bound by the part 2 regulations, among other requirements. We also refer the commenter to § 2.13(a), which states that any disclosures made under the regulations must be limited to that information that is necessary to carry out the purposes of the disclosure. As we have previously stated, to comply with § 2.13, lawful holders should ensure that the purpose section of the consent form is consistent with the role of or services provided by the contractor or subcontractor (*e.g.* ''payment and health care operations'') (83 FR 244).

Public Comments

One commenter requested additional clarification that a qualified service organization (QSO) under § 2.11 can provide the same health care operation services that will now be codified in § 2.33 for contractors of non-part 2 programs.

SAMHSA Response

A QSO is an individual or entity who provides services to a part 2 program consistent with a qualified service organization agreement (QSOA). Examples of services provided by QSOs include data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy. We believe many of these activities would overlap with those articulated in § 2.33(b) related to information disclosures to a lawful holder's contractors, subcontractors and legal representatives for the purposes of payment and/or health care operations.

Public Comments

One commenter recommended that SAMHSA clarify the term ''information which is necessary to carry out the stated purpose'' in regard to activities related to training of student trainees and healthcare professionals; business planning and development; management; and customer services. Alternatively, the commenter suggested that the regulations could require that these individuals use the part 2 information in a manner that is compliant with the HIPAA privacy regulations.

SAMHSA Response

Under § 2.33(b), disclosures to a lawful holder's contractors, subcontractors and legal representatives for payment and health care operations must be limited to that information which is necessary to carry out the stated purpose of the disclosure. This provision helps to ensure that information is not shared more broadly than the purposes for which the patient consents. Thus, disclosures for any of the activities under § 2.33(b) must be limited to that minimal amount of information that is truly necessary to carry out the purpose of the specific health care and payment operations activity intended. Likewise, under § 2.13(a), information disclosed under the part 2 regulations must be limited to that information which is necessary to carry out the purpose of the disclosure. To comply with § 2.13, we have previously stated that part 2 programs and lawful holders disclosing information under § 2.33(b) should ensure that the purpose section of the consent form is consistent with the role of or services provided by the contractor or subcontractor (*e.g.* ''payment and health care operations'') (83 FR 244).

At this time, we note that this rule provides transitional regulations until such time as implementing regulations for § 3221 of the CARES Act come into effect. In future rulemaking, we will consider making further revisions to § 2.33, consistent with the CARES Act.

Public Comments

A few commenters requested additional clarity on the types of activities that are permitted. Commenters suggested expanding the list and providing examples of

permitted activities, as well as describing expectations for activities that are not on the list. One commenter suggested that, rather than listing the 17 activities, the language ''unless explicitly prohibited'' would provide more clarity. A few commenters said SAMHSA should be clearer that the list is not all-inclusive.

One commenter asked that several items on the list of permitted activities be clarified to include specific activities. The commenter asked that the second item on the list, clinical professional support services (*e.g.,* quality assessment and improvement initiatives, utilization review and management services), be further clarified to include the calculation of quality measures and creation of appropriate benchmarks; that the third item on the list, patient safety activities, be further clarified to include determination of drug-drug interaction and notification of a prescriber and pharmacy provider if a medication is being prescribed that would be contraindicated for an individual receiving MAT; that the fourth item on the list, activities pertaining to training, practitioner assessment and practitioner plan performance, and training of non-health care professionals, be clarified to permit health plans and their contractors to make site visits and review records of a part 2 program provider as part of the accreditation process and reaccreditation process; and that the 13th item on the list, business planning and development, including the development or improvement of methods of payment or coverage policies, include activities related to the development and implementation of delivery system and payment reform. One commenter asked SAMHSA to clarify that this section would allow part 2 claims information to be utilized to evaluate whether an individual is an appropriate candidate for a prescriber or pharmacy restriction program.

SAMHSA Response

SAMHSA is finalizing in regulatory text under § 2.33(b) an illustrative and lengthy set of categories of activities for which lawful holders would be allowed to further disclose the minimal information necessary to contractors, subcontractors, or legal representatives for payment and health care operations. SAMHSA expects that this list will provide needed direction and guidance to stakeholders about the reasons for which information may be disclosed under this section, and its broad language should also provide flexibility for stakeholders to carry out necessary activities within each category to provide part 2 patients with quality care. SAMHSA believes the categories are largely self-explanatory, and we decline to list examples of all the potential activities that fit within each category, given the variation in and the evolving nature of the health care delivery system. SAMHSA does expect that additional payment and health care operations activities beyond those explicitly named would be permitted under § 2.33, and thus we are finalizing our proposal to add a final item to the list, indicating that other payment and health care operations activities not expressly prohibited are also allowed. The final item is intended to help ensure that stakeholders understand the list is not exclusive.

Public Comments

A commenter asked if activities described in § 2.33(b)(1)–(3) are only permissible with written patient consent, and if any of these activities fall under § 2.12(c)(3). The commenter believed a part 2 program needs consent before it shares information for operational activities such as supervision, training, quality assurance, peer review, etc. with an entity having direct administrative control over it.

SAMHSA Response

The activities listed in § 2.33(b) require a patient's consent to disclose his or her information for payment and health care operations. However, the part 2 regulations provide leeway for part 2 programs to share information within their larger health care organizations. Section 2.12(c)(3) states that, ''The restrictions on disclosure in the regulations in this part do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients with SUDs if the communications are: (i) Within a part 2 program; or (ii) Between a part 2 program and an entity that has direct administrative control over the program.'' The phrase ''direct administrative control'' refers to the situation in which a substance use disorder unit is a component of a larger behavioral health program or of a general health program.'' Additionally, under § 2.53(a)(2), part 2 programs may determine that individuals or entities within their health care organizations are qualified to conduct audits and evaluations and may share information pursuant to such reviews. Further, information may be shared for audit and evaluation purposes under new § 2.53(a)(1)(iii) and (b)(2)(iii) with entities that have direct administrative control over part 2 programs.

Public Comments

Several commenters opposed the change, stating that it has the potential for strong negative impacts to patients who may not fully understand to what they are consenting; would greatly expand the number of redisclosures without consent, including to entities that are not involved in direct patient care; and make it more difficult to respond to emerging practices that threaten patient privacy. One commenter said that aside from treatment purposes and a business associate-styled exception (with protections) for EMR and HIE vendors, disclosures should generally require written consent of the patient. Another said that the proposed change would permit disclosure without consent so broadly as to undercut the idea of protections and make the rules unenforceable as injured parties would not be able to identify who violated the rules. One commenter said it may be more appropriate for the agency to provide the illustrative list of activities that fall under ''payment and health care operations'' as regulatory guidance instead of including it in the regulation itself, as publishing the list as guidance may enable providers to feel more comfortable participating in activities not explicitly listed, but important to providing coordinated patient care.

SAMHSA Response

SAMHSA recognizes that lawful holders of part 2 information have legitimate needs to disclose that information to contractors, subcontractors and legal representatives, which play an integral role in the management, delivery and payment of health care services. The list of permitted activities was initially finalized as guidance in the 2018 final rule preamble. SAMHSA has learned that including an illustrative list of permissible activities in the preamble rather than in the text of the regulation did not fully clarify the circumstances under which part 2 information could be further disclosed under § 2.33. Specifically, stakeholders may believe that a particular activity is not permissible unless it is explicitly identified within the regulatory text. SAMHSA is now codifying the list in the regulatory text for added clarity. SAMHSA believes it has struck the correct balance between protecting patient confidentiality and ensuring that lawful holders involved in providing and paying for SUD treatment can reasonably function in today's complex

health care delivery framework. While § 2.33(b) allows for disclosures to contractors, subcontractors and legal representatives for health care payment and operational activities, SAMHSA has also placed limits on disclosures of part 2 information to such entities for such purposes. Specifically, § 2.33(c) outlines contract provisions for disclosures made under § 2.33(b) ensuring that that contractors, subcontractors or voluntary legal representatives are fully bound by part 2, among other requirements.

Public Comments

A few commenters said that the activities included in the term ''health care operations'' are so wide-ranging that they could be interpreted as permitting activities that could harm SUD patients by potentially allowing protected SUD information to be disclosed to employers. Commenters recommended the inclusion of anti-discrimination protection language in this section.

SAMHSA Response

As we have previously indicated, promulgating rules that address discriminatory action is outside the scope of SAMHSA's legal authority (83 FR 248). However, we refer the commenter to § 2.13(a), which states that patient records subject to the part 2 regulations may be disclosed or used only as permitted by the regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Further, §§ 2.64 and 2.65 describe required procedures and criteria for orders authorizing disclosures for criminal investigations of patients and for non-criminal purposes (such as a civil action).

Public Comments

One commenter said that although this section does not cover care coordination or case management, other clarifications in the proposed rule address those questions sufficiently.

SAMHSA Response

We appreciate this comment, but we also refer to our response below with regard to the addition of care coordination and case management to the list of permitted activities under § 2.33(b).

Public Comments

Many commenters objected to the exclusion of care coordination and case management under § 2.33(b) and asked SAMHSA to align its policy with the HIPAA privacy rule by including these activities in the definition of health care operations, or to otherwise allow care coordination and case management to be included in the list of permitted activities. A few commenters specifically noted that SAMHSA has the authority under 42 U.S.C. 290dd–2 to enact this change. One commenter suggested these activities be reclassified as health coaching or other legitimate health plan operational activities in order to ensure the appropriate coordination of care, while another urged SAMHSA to adopt a specific care coordination exception to the consent requirement.

Commenters gave many reasons for objecting to the exclusion of care coordination and case management from the list of permitted activities. Some commenters said the current policy is harmful to individuals with SUDs because it increases the risk of negative drug interactions, medical errors, overdose, or death; creates delays in care or in the receipt of MAT; and maintains and reinforces the stigma of SUD. Other commenters stated that disallowing care coordination and case management from the list of permitted activities is inconsistent with best practices and incompatible with the way health care is delivered today, hindering the ability to provide comprehensive, integrated, coordinated care that decreases emergency room and inpatient services. Commenters emphasized that optimal, safe care requires access to a patient's entire treatment history and current medications. Some commenters said that the current policy prevents insurers, Medicaid agencies, administrators, peer support organizations, and providers from making a more meaningful personal care impact and creates more difficulty in helping patients obtain better health outcomes.

A few commenters said the current rule causes confusion and administrative burden for providers as well as health plans that have difficulty obtaining written consent from enrollees, patients who must sign multiple consent forms, and other parties involved with the provision of health care. A few commenters also emphasized that the current policy is misaligned with HIPAA and that allowing for care coordination and case management under § 2.33(b) would ease administrative burden for entities subject to both part 2 and HIPAA. Another commenter said it would avoid the ''slippery slope'' of possibly expanding the proposed part 2 applicability changes to other non-part 2 lawful holders and for purposes beyond TPO. A few commenters also said that established definitions of ''care coordination'' and ''case management'' do not refer to treatment, diagnosis and referral, but instead refer to more operational, or management-based activities.

Several commenters emphasized potential benefits of including care coordination and case management in the list of permitted activities, such as increasing access to integrated, whole-person care; improving treatment adherence and outcomes; enabling managed care organizations to more easily provide valuable supports to their beneficiaries with SUD; avoiding duplicative prescriptions; facilitating communication with appropriate community-based organizations; alleviating complex consent requirements; and lowering overall health care costs. Another commenter said that recovery should be coordinated to address self-care practices, family, housing, employment, transportation, education, clinical treatment for mental disorders and SUDs, services and supports, primary healthcare, dental care, complementary and alternative services, faith, spirituality, creativity, social networks, and community participation.

One commenter said that SAMHSA has offered no legal or policy basis for this unique definition and handling of care coordination and case management for SUDs. A few commenters felt that part 2 limits or prohibits sharing of SUD records for critical care coordination activities while allowing it for less essential payment and health care operations. One commenter emphasized that SUD treatment providers must be treated equally—or with parity—to other health care providers. Others observed that changing the current policy would be consistent with the proposal's goals of improving appropriate information flow and integrated care and is philosophically aligned with CMS' and HHS' broader efforts to create a more integrated and efficient care delivery system.

SAMHSA Response

SAMHSA understands and acknowledges the commenters' concerns. SAMHSA recognizes that care coordination activities have numerous benefits described by the commenters, including the ability to protect patient safety, improve quality of care, and lower costs. SAMHSA also recognizes, consistent with commenter feedback, that many activities involving care coordination and case management are operational in nature, and distinguishable from the direct

disclosure of a treatment record from one provider (*e.g.,* a part 2 program) to another (*e.g.,* a non-part 2 primary care physician) for the purpose of treatment and diagnosis.

Because of the public comments that SAMHSA received on this issue in the proposed rule and the CARES Act amendments incorporating into 42 U.S.C. 290dd–2 provisions permitting disclosure of part 2 information for care coordination and case management activities, SAMHSA has decided to add care coordination and case management to the list of examples of permissible activities under the heading of payment and health care operations in § 2.33(b) in the regulatory text of the final rule. Under the final provision, a lawful holder who receives an SUD record subject to a patient's written consent may further disclose that record to its contractors, subcontractors, and/or legal representatives, for the purpose of carrying out care coordination or case management services in support of health care payment or operations. In order to avoid confusion about the extent of § 2.33(b), SAMHSA has also deleted from the regulatory text the statement that ''Disclosures to contractors, subcontractors, and legal representatives to carry out other purposes such as substance use disorder patient diagnosis, treatment, or referral for treatment are not permitted under this section.'' The revised, final rule language of § 2.33(b), taken on its face, applies to a patient's consent to a disclosure of his records for the purpose of payment and/or health care operations.

With regard to the revised, final rule language of § 2.33(b), we also note that the passage of the CARES Act by Congress will result in a major change to the authorizing statute, and will provide far greater flexibility for patients and health care providers to share SUD records than currently allowed under 42 U.S.C. 290dd–2. The revised, final rule language of § 2.33(b) represents an interim and transitional step towards more flexibility in consented-to disclosures for purposes of care coordination and case management, consistent with the realignment to the HIPAA privacy rule that is required by several provisions under the CARES Act. Again, HHS intends to publish a new NPRM and subsequently to issue final implementing regulations for the CARES Act in the future.

In the interim, note also that several other sections of this final rule, particularly at § 2.11 and § 2.12, separately will help to facilitate instances in which a care coordination activity is intermediated by a disclosure directly from a part 2 program to a non-part 2 provider for the purpose of treatment.

Public Comments

A few commenters said it is unclear whether care coordinators can be considered to have a treating provider relationship with the patient for purposes of the general designation option, and/or that they should be recognized as having a treating provider relationship for the purposes of part 2. One commenter said that this ambiguity is particularly challenging for accountable care organizations (ACOs), as patients may be passively attributed to the ACO and may not recognize the ACO's role in coordinating his or her care. The commenter requested that SAMHSA clarify under what circumstances an ACO can use disclosed part 2 information when the patient often is unaware that he/she is participating in the ACO due to passive attribution.

SAMHSA Response

As SAMHSA has previously indicated, individuals and entities that meet the definition of having a treating provider relationship with the patient are considered treating providers. The determination is fact-specific. (82 FR 6082). SAMHSA declines to explicitly broaden the term ''treating provider relationship'' to include all persons and entities that engage in any form of care coordination activity in this final rule. However, SAMHSA also has noted previously (82 FR 6085) that the definition of ''treating provider relationship'' is sufficiently broad to cover the necessary components of a patient's care team. SAMHSA may provide further sub-regulatory guidance in the future with regard to ACOs, if further clarification is needed.

Public Comments

A few commenters suggested that SAMHSA allow part 2 records to be disclosed for the purposes of care coordination with specific written patient consent that is clear and understandable. A few commenters said that SAMHSA could permit the use of a one-time, generalized consent that would allow for the disclosures and redisclosures for treatment, payment, and health care operations purposes to HIPAA-covered entities and part 2 programs. Similarly, a commenter emphasized that allowing general consent to share SUD information with caregivers for ''other treatment'' purposes, including placement and care coordination, would reduce the significant administrative burden associated with generating a specific consent prior to each instance that this information is shared with caregivers. Another commenter recommended that SAMHSA revise 42 CFR 2.33(b) to allow lawful holders that receive part 2 records pursuant to a patient's consent to disclose such information to their contractors, subcontractors, and legal representative for ''all purposes authorized by the patient.'' One commenter urged SAMHSA to adhere to the American Academy of Family Physicians' (AAFP's) policy on Patient/Physician Confidentiality regarding the privacy of medical information, and specifically that third-party payer and self-insured employer policies and contracts should explicitly describe the patient information that may be released, the purpose of the information release, the party who will receive the information, and the time period limit for release.

SAMHSA Response

As explained above, SAMHSA has made a change to the regulatory text of § 2.33(b), to add care coordination and case management to the list of examples of permissible disclosures under the heading of payment and operations. Under the final provision, a lawful holder who receives an SUD record subject to a patient's written consent may further disclose that record to its contractors, subcontractors, and/or legal representatives, for the purpose of carrying out care coordination or case management services in support of health care payment or operations. SAMHSA believes that this revision to § 2.33(b) will strike the appropriate balance in facilitating disclosures with patient consent, for the purpose of operational care coordination and case management activities. SAMHSA believes that it is beyond the scope of the current rule-making to address AAFP's policy, with regard to instituting new requirements for third-party payer and self-insured employer policies and contracts, and thereby describing and limiting any corresponding release of information from patient records.

Public Comments

One commenter expressed concern that SAMHSA has also continued to exclude diagnosis, treatment, and referral to treatment from the proposed rule's definition of health care operations, and urged SAMHSA to further revise the rule to include these critical activities in its definition of health care operations.

SAMHSA Response

SAMHSA is making a change to § 2.33(b) in the final rule addressing these issues, as described above.

Public Comments

A few commenters advocated that 42 CFR part 2 be brought into full alignment with HIPAA, saying it would streamline consents; reduce barriers to data sharing, care coordination and treatment; and maintain appropriate privacy protections. Commenters emphasized that full alignment with HIPAA would better reflect current health care operations as well as legal and social healthcare policy. One commenter said that the HIPAA privacy framework includes protections for healthcare records, conversations with providers about care decisions or treatment, and personal information, such as billing information. Another commenter noted that providers have years of experience with the HIPAA framework, have processes in place to ensure that coverage and treatment information is protected, and face the risk of enforcement penalties under HIPAA. A few commenters urged SAMHSA to allow part 2 records to be shared without re-disclosure restrictions as long as any re-disclosures are for similar treatment, payment and health care operations purposes, or alternatively that SAMHSA include the sharing of medical records from part 2 providers with HIPAA-covered providers, health plans and care coordination entities without patient consent, including the exchange of that information through Health Information Exchanges. Another commenter recommended that if such streamlining cannot be accomplished, SAMHSA provide further guidance to industry regarding ways in which important patient care objectives can still be achieved despite the restrictions.

SAMHSA Response

Due to its targeted population, part 2 provides more stringent federal protections than most other health privacy rules, including HIPAA. In light of the part 2 authorizing statute and its intent, SAMHSA is unable to create the alignment suggested by the commenters. However, in this final rule, SAMHSA does make numerous revisions to the part 2 regulations that will improve information sharing among a patient's treating providers, which should enhance the ability to coordinate care and better serve patients receiving treatment from part 2 programs. In this regard, we also note that the current rule provides a transitional standard until such time as implementing regulations for § 3221 of the CARES Act come into effect. In future rulemaking, we will consider making additional revisions to § 2.33, as needed to implement relevant provisions under the CARES Act.

Public Comments

One commenter suggested clarifying that a patient does not need to complete the ''purpose'' section of a 42 CFR part 2-compliant consent form for it to be a valid authorization. The commenter said that denying a patient-directed release of information because the patient has failed to complete this section is not appropriate or consistent with SAMHSA's commitment to ''patient choice in disclosing information.''

SAMHSA Response

We disagree with the commenter. Section 2.31(a)(5) requires the consent to include the purpose of the disclosure. Section 2.31(b) states that a disclosure may not be made on the basis of a consent which on its face substantially fails to conform to any of the requirements set forth in § 2.31(a).

Public Comments

Several commenters offered ideas for topics that future regulations or guidance could address, including phone screenings; new care models; the use of digitized voice consent; and a templated, plain language part 2 record consent form that could be used to better standardize disclosures, provided in an electronic format that would allow populated data to be easily integrated into information management systems.

SAMHSA Response

We thank the commenters for their suggestions and will consider these ideas for future guidance.

G. Disclosures To Prevent Multiple Enrollments (§ 2.34)

SAMHSA is finalizing this section as proposed.

In the 2017 final rule, SAMHSA modernized § 2.34 by updating terminology and revising corresponding definitions. Section 2.34 permits, with consent, disclosure of patient records to a withdrawal management or maintenance treatment program within 200 miles of a part 2 program. After considering comments, we retained the specificity of ''200 miles'' to prevent multiple enrollments that could result in patients receiving multiple streams of SUD treatment medications, which in turn may increase the likelihood of an adverse event or of diversion (82 FR 6094).

Central registries, defined in § 2.11, do not exist in all states, and the defining parameters for the operation of the registries vary somewhat across states and across part 2 programs. However, in the context of the opioid epidemic, recent experience has demonstrated that it is important for all providers who work with SUD patients, including non-opioid treatment program (non-OTP) providers, to have access to the information in the central registries, for the purpose of helping prevent duplicative patient enrollment for opioid use disorder treatment. Access to central registry information is also needed by non-OTP providers to fully inform their decisions when considering appropriate prescription drugs, including opioids, for their patients.

Methadone is a long-acting opioid used to treat opioid use disorders and for pain that, when used at levels higher than recommended for an individual patient, can lead to low blood pressure, decreased pulse, decreased respiration, seizures, coma, or even death. When used as a part of a supervised MAT program, methadone is a safe and effective treatment for SUD, including opioid use disorder (OUD). Methadone is a long-acting opioid, subject to accumulation when its metabolism is inhibited. Its effects may be potentiated by certain other drugs with which it may have pharmacodynamic interactions, so the medication is specifically tailored to each individual patient and must be used exactly as prescribed. Exceeding the specific dosing can lead to dangerous side effects and potential overdose. Other medications, including other SUD treatments, such as buprenorphine, as well as other medication including other opioids, benzodiazepines, HIV medications, certain antipsychotics and anti-depressants, also have the potential to interact dangerously with methadone.

Buprenorphine products are also long-acting opioid formulations approved by FDA for treatment of opioid use disorder, subject to limitations, which can be dispensed at OTPs, and in outpatient settings. While buprenorphine is demonstrated to exhibit a ceiling effect on respiratory depression in persons with opioid tolerance, it has significant opioid effects in those without tolerance which can contribute to adverse events including opioid overdose. Both of these long acting opioids (methadone and buprenorphine) have potential drug interactions with other medications that could lead to adverse events, including drug toxicity and opioid overdose.

These realities underscore the reason it is important for a prescriber to check

central registries, when possible, to assure that it is appropriate to prescribe the contemplated opioid therapies for a particular individual. The ability to query a central registry regarding any duplicative enrollment in similar treatment can also be crucial to effective care, and to ensuring patient safety. Similarly, to avoid opioid-related adverse events, it is imperative that prescribing clinicians be aware of any opioid therapy that may be in current use by a patient prior to making further medication prescribing decisions.

Under the current language of § 2.34(a), a part 2 program may seek a written patient consent in order to disclose treatment records to a central registry. In turn, the recipient central registry may only disclose patient contact information for the purpose of preventing multiple enrollments under § 2.34(b). Currently, under § 2.34(c), the central registry may only disclose when asked by a ''member program'' whether an identified patient is enrolled in another member program.

SAMHSA proposed to expand the scope of § 2.34 to make non-OTP providers with a treating provider relationship with the patient eligible to query a central registry to determine whether the specific patient is already receiving opioid treatment through a member program to prevent duplicative enrollments and prescriptions for excessive opioids, as well as to prevent any adverse effects that may occur as a result of drug interactions with other needed medications. Specifically, SAMHSA proposed to amend § 2.34(b) to include the use of central registry information to coordinate care with a non-part 2 program. In addition, we proposed to add a new subsection (d) to specifically permit non-member treating providers to access the central registries. Previous subsection (d) would be re-designated as subsection (e).

SAMHSA believes that disclosures by central registries to non-OTP treating providers will help to ensure patient safety, and to prevent duplicative treatment plans and medications or medication doses that could place a patient receiving SUD treatment at risk.

The comments we received on the proposed amendments to § 2.34 and our responses are provided below.

Public Comments

Many commenters believed the proposed changes will prevent duplicative prescriptions, avoid adverse drug events, ensure patient safety, foster care coordination, and improve care quality.

SAMHSA Response

SAMHSA appreciates the comments and agrees that the finalized changes will give all providers with a treating relationship important information for treating patients with SUD, thereby increasing coordination and quality of care and improving patient safety.

Public Comments

A few commenters expressed concern that the proposed changes, if finalized, would reduce patient privacy and increase stigma and harm. Some commenters drew a distinction between changes proposed in § 2.36 and changes proposed in this section, noting that sharing information from central registries would infringe upon patient privacy protections in a way that contravenes 42 CFR part 2. One commenter expressed concern that the proposed changes are unnecessary and that medication information can be gathered through drug screens.

SAMHSA Response

SAMHSA is committed to improving the lives of people living with SUD, and individuals with SUD face real stigma. We believe that allowing medical professionals with a treating provider relationship access to central registries will improve the quality and safety of care for these individuals. We also believe that increasing care coordination and information access within an individual's care team will reduce stigma by giving providers accurate and comprehensive information about a patient's medical needs. We appreciate commenters' concerns regarding patient privacy and remain dedicated to protecting information for individuals with SUD. SAMHSA believes that privacy cannot come at the cost of patient care and safety, and the proposed changes seek to balance the critical importance of patient confidentiality with the vital information required for medical professionals to provide the highest quality care to individuals with SUD. We also note that central registries already exist as defined in § 2.11 and the proposed changes in this rule would not create new registries. SAMHSA acknowledges that some information can be obtained from patient drug screens. However, accurate dosing and frequency of medications cannot be obtained from drug screens and these types of screens do not offer a reliable substitute for the proposed changes.

Public Comments

A few commenters in §§ 2.34 and 2.36 expressed concern about the concept of central registries, and noted that they were opposed to requiring patients with SUD to be listed on a registry.

Several commenters requested clarification on the process to obtain consent for the proposed changes. Other commenters requested clarification on how the proposed changes would or would not compel corresponding changes in state law to permit access to central registries.

A few commenters requested clarification on the privacy protections afforded to information obtained by non-OTP providers from central registries if the information in the non-OTP record is not segmented. Some of these commenters also asked if the access to central registries was limited to physicians or open to other health care professionals with a treating provider relationship such as physician assistants or nurse practitioners.

SAMHSA Response

As noted earlier, SAMHSA understands the concerns of these commenters and would like to clarify that central registries as defined under § 2.11 already exist within OTPs and are used solely for the purpose of maintaining health care information. The proposals within this section would not create new requirements that compel patients with SUD to register on any lists.

SAMHSA anticipates that OTPs may update existing consent forms to include new language regarding information shared with non-OTP treating providers, or create new consent forms for this purpose. It is SAMHSA's understanding that while many state laws do not inherently prevent access to central registries, some states may consider legal updates to ensure that non-OTP providers are not expressly prohibited from such access.

We appreciate commenter questions regarding the privacy protections afforded to information shared with non-OTP providers. Central registry information consists primarily of basic patient contact information and medication and dosage information limited to any treatment an individual is receiving from that OTP. Any information recorded by a non-OTP provider in her own practice's patient record originating from a central registry query would be similarly limited. We anticipate that a non-OTP provider would discuss a patient's SUD treatment history at a specific OTP prior to querying that OTP's central registry. Therefore, any information obtained from the central registry query will supplement information provided by the patient in that encounter with the non-OTP provider. While SAMHSA

does not limit central registry queries to physicians, any non-OTP providers including physicians and non-physician (*i.e.* nurse practitioners, physician assistants) must demonstrate a treating provider relationship in accordance with relevant state law prior to querying a central registry.

Public Comments

A few commenters noted that while they are supportive of the proposed changes to permit non-OTP providers access to central registries, they would prefer the language in § 2.34 to require central registries to report to non-OTP treating providers. A few commenters expressed a preference for requiring such reporting without patient consent to ensure information accuracy, noting that permitting such reporting does not go far enough to protect patient safety. One commenter suggested that Part 2 programs be required to undertake such reporting in addition to central registries.

SAMHSA Response

We appreciate these comments and understand concerns that these proposed changes offer maximum impact for patient safety and information accuracy. Central registries vary widely. Some states may operate robust central registries while others may have more limited capabilities or may not operate a central registry at all. Given this variation, it is infeasible to require central registries or part 2 programs to report to external non-part 2 providers. Furthermore, SAMHSA has no authority under 42 U.S.C. 290dd–2 to impose such a requirement and declines to do so at this time.

Public Comments

One commenter recommended that SAMHSA utilize existing health information exchanges or networks to coordinate queries to central registries.

A few commenters recommended that SAMHSA establish minimum standards for central registries and require OTP participation in a central registry. These commenters noted that while the proposed changes will improve care coordination and patient safety, the lack of standardization and wide variation across central registries creates challenges for all providers treating patients with SUD. Some of these commenters stated that they were not aware of any central registries in their area even though they were aware of OTPs providing SUD services and requested that SAMHSA reconsider the role of central registries.

SAMHSA Response

We will consider these suggestions and continue to assess opportunities to improve the operational efficiency and efficacy of central registries.

H. Disclosures to Prescription Drug Monitoring Programs (§ 2.36)

SAMHSA is finalizing this section as proposed.

A prescription drug monitoring program (PDMP) is a statewide electronic database that collects, analyzes, and makes available prescription data on controlled substances prescribed by practitioners and non-hospital pharmacies.[6] Forty-nine states, St. Louis County, Missouri [7] and the District of Columbia have legislatively mandated the creation of PDMPs. Most states had developed their own PDMP prior to the current opioid crisis; however, few prescribers accessed them.[8] As opioid use disorder rates, overdoses and deaths increased significantly since 1999, the majority of states began requiring health professionals to check the state's PDMP [9] before prescribing controlled substances to patients. Currently, 41 states require physicians to use their state's PDMP to analyze prescription history prior to writing a prescription for opioids or other controlled substances.[10] Studies have shown that states that have implemented such a requirement have seen declines in overall opioid prescribing, drug-related hospitalizations, and overdose deaths.[11]

Most PDMPs track prescription drug information on Schedule II–V controlled medications. Pharmacies must submit the prescription data required by their state's PDMP, depending on the state's statutory requirements. More robust PDMP programs have been associated with greater reductions in prescription opioid overdoses.[12] As noted above, this data allows providers to ensure that a patient is not receiving multiple prescriptions and to enhance patient care and patient safety.

Presently, OTPs are not required to report methadone or buprenorphine dispensing to their states' PDMP. In our 2011 guidance letter, SAMHSA encouraged OTP staff to access PDMPs, but stated that OTPs could not disclose patient identifying information to a PDMP unless an exception applies, consistent with the federal confidentiality requirements.[13] SAMHSA no longer believes this policy is advisable in light of the current public health crisis arising from opioid use, misuse, and abuse. In the past 10 years, there has been a substantial increase in prescription drug misuse, admissions to substance use facilities, emergency department visits and opioid-related deaths.[14] The omission of OTP data from a PDMP can lead to potentially dangerous adverse events for patients who may receive duplicate or potentially contraindicated prescriptions as part of medical care outside of an OTP, thereby placing them at risk for adverse events, including possible overdose or even fatal drug interactions.

SAMHSA believes that permitting part 2 programs, including OTPs, and lawful holders to enroll in PDMPs and submit the dispensing data for controlled substances required by states currently for other prescribed, controlled substances would allow for greater patient safety, better patient treatment, and better care coordination among the patient's providers. Therefore, SAMHSA proposed to add a new section § 2.36, permitting part 2

[6] SAMHSA's Center for the Application of Prevention Technologies; Using Prescription Drug Monitoring Program Data to Support Prevention Planning. Available at: *https://www.samhsa.gov/capt/sites/default/files/resources/pdmp-overview.pdf.*

[7] Former Missouri Gov. Greitens ordered the creation of a statewide PDMP in July 2017, but state lawmakers have not yet authorized funding for the program. St. Louis County started its own PDMP in April 2017, which covers nearly 80 percent (28 counties and 6 cities) of Missouri physicians and pharmacists.

[8] Brandeis University Prescription Drug Monitoring Program Training and Technical Assistance Center. Available at: *http://www.pdmpassist.org/pdf/Resources/Briefing_on_mandates_3rd_revision_A.pdf.*

[9] Pew Charitable Trusts and National Alliance for State Model Drug Laws. Available at: *https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2017/12/29/in-opioid-epidemic-states-intensify-prescription-drug-monitoring.*

[10] Pew Charitable Trusts. When are Prescribers Required to Use Prescription Drug Monitoring Programs? January 24, 2018. Available at: *https://www.pewtrusts.org/en/research-and-analysis/datavisualizations/2018/when-are-prescribers-required-to-use-prescription-drug-monitoring-programs.*

[11] Brandeis University Prescription Drug Monitoring Program Training and Technical Assistance Center. Available at: *http://www.pdmpassist.org/pdf/Resources/Briefing_on_mandates_3rd_revision_A.pdf.*

[12] Pew Charitable Trusts. When are Prescribers Required to Use Prescription Drug Monitoring Programs? January 24, 2018. Available at: Available at: *https://www.pewtrusts.org/en/research-and-analysis/datavisualizations/2018/when-are-prescribers-requiredd-to-use-prescription-drug-monitoring-programs.*

[13] Clark HW. Dear Colleague letter. September 27, 2011. Available at: *https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2011-colleague-letter-state-prescription-drug-monitoring-programs.pdf.*

[14] SAMHSA. In Brief: Prescription Drug Monitoring Programs: A Guide For Healthcare Providers. Volume 10, Issue 1 (Winter 2017). Available at: *https://store.samhsa.gov/system/files/sma16-4997.pdf.*

programs, OTPs and other lawful holders to report the required data to their respective state PDMPs when dispensing medications with written consent from the patient whose identifying information will be disclosed prior to making such reports. This update is consistent with the proposal under § 2.34(c) to allow non-OTPs to query central registries to prevent duplicate enrollment.

SAMHSA acknowledges that the proposed provision may raise concerns about law enforcement access to PDMPs, particularly in those states in which PDMPs are operated by a law enforcement agency. However, individuals are not limited to OTPs when seeking OUD treatment. Prescriptions written for OUD opioid pharmacotherapy by non-OTP providers are already recorded in the state PDMP. By implication, PDMPs operated by law enforcement agencies are already receiving some patient data related to SUD treatment. Although the current proposal might expand that practice, it would not create it. And because the disclosure of SUD patient records by OTPs would be made contingent on written patient consent, any negative impact on patient confidentiality seems likely to be small. By contrast, the omission from PDMPs of dispensing and prescribing data from OTPs presents serious safety risks for SUD patients. While the reporting of patient data to a PDMP by an OTP would make it possible for law enforcement, prescribers, and pharmacies with access to a PDMP to determine that a specific patient had received services at a specific OTP, law enforcement would still require a court order meeting the requirements of § 2.65 to access the covered records of that patient or any other patient served at the OTP. SAMHSA believes that allowing for OTP reporting to PDMPs further enhances PDMPs as a tool to help prevent prescription drug misuse and opioid overdose, while providing more complete and accurate data. In turn, more robust PDMP data is imperative for prescribers and providers to make better and more accurate patient care decisions while increasing patient safety and assuring appropriate care.

We note that, under § 3221(k) of the CARES Act, it is the sense of Congress that any person treating a patient through a program or activity with respect to which 42 CFR part 2 protections apply is encouraged to access the applicable PDMP when clinically appropriate. In future rulemaking, we will consider the possibility of making revisions to § 2.36, as needed to implement relevant provisions under the CARES Act. The comments we received on the proposed new provision of § 2.36 and our responses are provided below.

Public Comments

Many commenters supported the proposed changes, noting that PDMPs are an important tool for improving care coordination and safety for patients with SUD and that completeness of information is critical for all providers treating patients with SUD. Several commenters believed that this proposal will reduce deaths from adverse drug interactions. A few other commenters noted that many physicians and health care professionals are not aware that PDMPs do not currently contain comprehensive information on patient medications and they believed that this proposal is essential for improving patient care and safety, particularly for individuals receiving MAT.

SAMHSA Response

We appreciate the supportive comments and agree that the proposal will improve the quality and safety of care for individuals with SUD.

Public Comments

Many commenters opposed the proposed changes and expressed concerns about the potential breach of privacy patients may face and noted specific concerns regarding stigma, discrimination, and decreased likelihood of seeking treatment as a result of the proposed changes.

SAMHSA Response

As stated previously, SAMHSA is committed to improving the lives of people living with SUD, and individuals with SUD face real stigma. We believe that increasing care coordination and information access within an individual's care team will reduce stigma by giving providers accurate and comprehensive information about a patient's medical needs.

Public Comments

One commenter expressed concern about PDMP data being utilized for pre-employment physical examinations and Department of Transportation medical examinations and requested clarification on the appropriateness of PDMP data for occupational health purposes.

One commenter questioned the language in the proposed changes that includes medications prescribed and dispensed, noting that providers report only dispensed medications and not prescribed medications.

Several commenters requested SAMHSA to provide further clarification to states to legally permit OTPs to enroll in PDMPs in instances where doing so may currently contravene state PDMP laws or where state PDMP laws do not currently support OTP reporting.

Some of these commenters noted that state PDMP capabilities vary and some systems have more robust information than others. These commenters encouraged SAMHSA to work with states to facilitate PDMPs that can accommodate the proposed changes.

A couple commenters requested clarification on the patient consent process given the changing nature of PDMP capabilities. One commenter expressed concern that a patient's willingness to consent may change if the components or capabilities of a PDMP also change, and this should be taken into consideration in the proposed changes.

One commenter requested clarification for states as they work to modernize PDMPs, and expressed concern about unfunded costs to states to operationalize PDMPs for the type of reporting in the proposed changes.

A few commenters requested clarification on whether consent to disclose to PDMPs would be a separate consent or if it could be added to existing patient consent documentation. Some of these commenters also requested clarification on the level of specificity required if a patient requests a list of entities per § 2.31. A couple of commenters requested clarification as to whether additional consent is required regarding redisclosure and the sharing of part 2 information to each PDMP registered end user. One commenter requested clarification on the decision to support OTP disclosures to PDMPs but not for the purposes of care coordination or case management under § 2.33.

SAMHSA Response

SAMHSA acknowledges concerns about the use of PDMP data for occupational health decisions. It is not the intention of SAMHSA to permit the use of SUD information in pre-employment occupational health examinations, although SAMHSA does not have the statutory authority to control how states choose to utilize the data captured within their PDMPs. We note, however, that pursuant to § 2.13(a), patient records subject to the part 2 regulations may be disclosed or used only as permitted by the regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative

proceedings conducted by any federal, state, or local authority. While many state PDMPs require information solely upon dispensing, some state PDMP laws require prescribers to enter information at the point of prescribing and our language reflects the variation in these laws.

SAMHSA appreciates comments regarding PDMP capabilities and variations across states. Because PDMPs are operated by each state, it will be up to each state to update PDMP laws in a way that permits OTPs to enroll in PDMPs and maintain systems that accommodate the needs of registered users.

We understand commenter concern regarding the consent process. PDMPs are updated to provide maximum usability and information accuracy. Inherent in a patient's consent is the understanding that a PDMP database is continuously updated with current prescribing and dispensing information. Part 2 programs may consider periodic updates to their consent forms to reflect any substantial changes to their state PDMP.

SAMHSA appreciates the costs to states as they modernize and update PDMPs. While the proposed changes may require some state PDMPs to adapt or adopt new capabilities, we note that the goal of PDMPs is to provide accurate, timely information on prescribing and dispensing. The evolving nature of medical and pharmaceutical care requires routine maintenance and updates and we do not believe these proposed changes exceed those obligations. SAMHSA anticipates that OTPs may update existing consent forms to include new language regarding information shared with non-OTP treating providers, or create new consent forms for this purpose. We do not expect the proposed changes to require additional consent for redisclosure to each registered PDMP end-user.

Changes proposed under § 2.36 require that the patient specifically consent to the disclosure to a PDMP. This is distinct from disclosures for care coordination under § 2.33, which require only that the patient generally consent to the part 2 program making a disclosure for payment and/or health care operations activities.

Public Comments

Several commenters requested that patient consent not be required because of the potential adverse effects on safety if an individual declines treatment due to the PDMP consent requirement and/or provides incomplete or inaccurate information as a result of the consent requirement. A few commenters requested that OTPs be required to report to PDMPs to provide the most complete information and to fill in gaps that may be created by varied PDMP usability and/or inconsistent standards and availability of central registry data.

SAMHSA Response

As stated previously, we appreciate these comments and understand concerns that these proposed changes offer maximum impact for patient safety and information accuracy. State operation of PDMPs and part 2 program operation of central registries vary widely. Furthermore, SAMHSA has no authority under 42 U.S.C. 290dd–2 to impose such a requirement and declines to do so at this time.

Public Comments

One commenter recommended leveraging the use of statewide HIEs and HINs to coordinate queries to central registries and PDMPs.

A few commenters recommended a national prescription drug monitoring database as an alternative to state-level PDMPs and central registries.

A few commenters noted that common industry standards for PDMPs would be valuable given their utility in fighting the opioid crisis. One of these commenters also noted that e-prescribing provides a valuable alternative to tracking opioid prescriptions. This commenter expressed concerns about the lack of interoperability between EHRs and PDMPs and noted that this could create barriers for clinicians attempting to use PDMPs in real-time during patient encounters.

One commenter recommended educating non-OTP providers as the proposed changes may bring individuals with SUD into contact with clinicians who are unfamiliar with OTP protocols, terms, benefits, and limitations.

One commenter recommended moving proposed changes related to PDMPs to § 2.31(a)(4)(B) to say, ''such as an entity that facilitates the exchange of health information, prescription drug monitoring program, or a research institution.''

A few commenters recommended notifying PDMP users that information related to medications dispensed from OTPs may still be incomplete as a result of patient consent requirements.

SAMHSA Response

SAMHSA appreciates suggestions from commenters to better facilitate the integration of PDMP reporting among OTPs. PDMPs are overseen by states, and SAMHSA does not govern their operation. We agree that OTPs may find benefit in educating providers about PDMPs and expect that the registration process will inform registered OTP users about the specific regulations governing the use and capabilities of the PDMP within their state. We also believe that non-OTP providers may benefit from education on SUD to become familiar with the unique needs of the patients they treat who may be living with SUD.

Public Comments

Many commenters expressed specific concerns regarding law enforcement access to PDMPs and shared fears of increased criminal prosecution or adverse legal action for patients with SUD. One commenter requested clarification on how a request for information regarding a specific patient traceable by the law enforcement agency with oversight of the PDMP to an OTP provider would be outside the definition of ''disclose'' in § 2.11.

A couple of commenters noted that specific guidance from SAMHSA reiterating that law enforcement may not seek individual patient records without a court order may be reassuring for patients. Other commenters noted that even though 42 CFR part 2 requires a court order from law enforcement to obtain individual patient records, many state PDMPs do not currently require a court order which could open a backdoor for law enforcement access without immediate changes to state PDMP law. Several commenters noted that while law enforcement may be required to obtain a court order before seeking additional records, sensitive inferences can be made from prescription records alone.

One commenter suggested that states with law enforcement agency oversight of the PDMP should move the operations to a different agency authority. A couple of other commenters suggested the addition of anti-discrimination language within § 2.36 that would provide more explicit protections against insurance, health care, and legal discrimination.

One commenter expressed concern about state laws that penalize pregnant or parenting women with SUD and noted that OTP reporting to PDMPs would create a significant disincentive for those women to seek necessary treatment.

SAMHSA Response

SAMHSA understands concerns from commenters regarding law enforcement interaction with PDMPs. As stated previously, PDMPs are overseen by states and SAMHSA does not govern

their operation. While we appreciate concerns about the challenges faced by individuals with SUD, especially with regard to interactions with law enforcement, we believe that allowing for OTP reporting to PDMPs further enhances PDMPs as a tool to help prevent prescription drug misuse and opioid overdose, while providing more complete and accurate data. This robust data is critical for providers and prescribers to make accurate and safe decisions for patient care. As stated in our response to similar comments on anti-discrimination language in response to the 2018 Final Rule, promulgating rules that address discriminatory action is outside the scope of SAMHSA's current legal authority (83 FR 248). With this being said, note that we anticipate revisiting § 2.36 in future rulemaking to implement the CARES Act, and we will continue to consider the concerns about PDMPs and law enforcement in that context.

I. Medical Emergencies (§ 2.51)

SAMHSA is finalizing this section as proposed.

Under § 2.51, disclosures of SUD treatment records without patient consent are permitted in a bona fide medical emergency. Although not a defined term under part 2, a ''bona fide medical emergency'' most often refers to the situation in which an individual requires urgent clinical care to treat an immediately life-threatening condition (including, but not limited to, heart attack, stroke, overdose), and in which it is infeasible to seek the individual's consent to release of relevant, sensitive SUD records prior to administering potentially life-saving care. SAMHSA proposed to amend this section to address the impact of major [15] and natural disasters, declared by state or federal authorities, on access to substance use treatment and services, in addition to the more common situation of an individual experiencing a ''bona fide medical emergency.''

Disasters (*e.g.,* hurricanes, wildfires) can present unique challenges for patients with SUDs, and for their treating providers. These events may disrupt the usual access to services and medications across a geographic region. As a result, patients may be required to seek treatment at facilities or with providers who do not have full access to their records.

When access to, or operation of, substance use disorder treatment facilities and services are disrupted on a regional basis in the wake of a disaster like a hurricane or wildfire, many patients become unable to access care through their usual providers, while many providers may be unable to follow usual consent-based procedures in order to obtain and/or release records for large numbers of patients. Thus, the disclosure requirements of 42 CFR part 2 may be too burdensome in these instances. For example, in the case of a hurricane, normal policies and procedures for obtaining consent according to §§ 2.31 and 2.32 may not be operational. At the same time, the inability of SUD patients to access needed care through their usual providers (or other providers) that have access to part 2-protected records concerning their condition, may constitute or lead to medical emergencies. As a result of these factors, SAMHSA stated in the 2019 proposed rule that we believe that it is necessary—and consistent with our statutory authority—to include natural and major disasters within the meaning of medical emergency for which there would be an exception to the requirement of consent for disclosure of part 2 records. In this final rule, such an exception is finalized.

SAMHSA underscores that consent should still be obtained if at all feasible, but appropriate care should be the priority in these often-devastating scenarios and an exception should be allowed. Thus, SAMHSA proposed to revise § 2.51(a) to facilitate expedient access to care for patients with SUDs during natural and major disasters. Specifically, SAMHSA proposed to authorize, under § 2.51(a), a part 2 program to disclose patient identifying information to medical personnel, without patient consent, as needed in the event of a natural or major disaster to deliver effective ongoing SUD services to patients in such disasters. Specifically, SAMHSA proposed that this medical emergency exception would apply only when a state or federal authority declares a state of emergency as a result of a disaster and the part 2 program is closed and unable to provide services or obtain the informed consent of the patient as a result of the disaster, and would immediately be rescinded once the part 2 program resumes operations.

The comments we received on the proposed amendments to § 2.51 and our responses are provided below.

Public Comments

Many commenters supported the proposal to amend § 2.51 to include natural and major disasters within the meaning of medical emergency for which there would be an exception to the requirement of consent for disclosure of part 2 records.

SAMHSA Response

We thank commenters for their support.

Public Comments

One commenter requested clarification whether a disaster would qualify as a medical emergency for every impacted patient. The commenter requested further clarification whether the closed part 2 program would need to determine if it is a medical emergency for each patient.

SAMHSA Response

If a patient's part 2 program has closed and is unable to provide services or obtain the written consent of the patient due to a state of emergency caused by a natural or major disaster, then that part 2 program may disclose part 2 patient records to other medical personnel to deliver effective ongoing SUD services. We note that consent should still be obtained if at all feasible. However, if the situation we describe above occurs, and the part 2 program is unable to obtain consent or to provide services, the part 2 program may consider the event a medical emergency and is permitted to disclose the part 2 records without patient consent. The exception would be rescinded when the part 2 program resumes operations.

Public Comments

One commenter recommended that SAMHSA develop further guidance on how patients and other medical personnel may be notified that the program is closed and unable to provide services or obtain consent. The commenter recommended that the guidance also include examples of how part 2 records may be disclosed to medical personnel in the event the program is closed. One commenter recommended that SAMHSA work with the HHS Office for Civil Rights to coordinate communication and outreach efforts regarding the proposals to § 2.51 to ensure that medical personnel and health information professionals are aware of the changes. One commenter also recommended that SAMHSA work with the HHS Assistant Secretary for Preparedness and Response (ASPR) and other federal and state agencies to communicate a clear ''start'' and ''end'' for these situations.

[15] The Federal Emergency Management Agency (FEMA) notes that the President can declare a major disaster for any natural event, regardless of cause, that is determined to have caused damage of such severity that it is beyond the combined capabilities of state and local governments to respond. *https://www.fema.gov/disaster-declaration-process.*

SAMHSA Response

We appreciate the commenters' suggestions. We will consider potential future options, including issuing further guidance and outreach as well as partnering with other HHS agencies, to ensure that medical personnel and other professionals are aware of the changes to § 2.51.

Public Comments

One commenter requested clarification on whether medical personnel includes peer recovery support personnel, recognizing that peer recovery support is a part of SUD treatment.

SAMHSA Response

Under the authorizing statute at 42 U.S.C. 290dd–2(b)(2)(A), part 2 records may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency. As stated in the 2017 Final Rule, it is up to the health care provider or facility treating the emergency to determine the existence of a medical emergency and which personnel are needed to address the medical emergency. The name of the medical personnel to whom the disclosure was made, their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the medical emergency must be documented in the patient's records by the part 2 program disclosing the information.

Public Comments

A few commenters requested that SAMHSA expand the definition of emergency for when disclosures to another part 2 program or SUD treatment provider is permitted. A few commenters noted that the proposal does not consider localized, serious events that could create similar barriers as a declared state or federal emergency. One commenter recommended allowing a discretionary determination that the Part 2 program is unable to provide services to the person or obtain consent due to a disaster. A few commenters recommended that providers who have a treating relationship should have the discretion to determine what constitutes an emergency. One commenter recommended that SAMHSA include ''man-made'' disasters, such as cyber-attacks when information systems and networks could be impacted. One commenter recommended that SAMHSA ensure the proposed changes during a natural disaster is aligned with HIPAA.

SAMHSA Response

We thank commenters for their suggestions. With regard to the request that a medical emergency be determined by the treating provider, SAMHSA clarifies that any health care provider who is treating the patient for a medical emergency can make that determination.

Public Comments

One commenter recommended expanding the proposal to include waivers from the part 2 requirements, safe-harbor from penalties and enforcement for entities who follow these processes in good faith and public health emergencies.

SAMHSA Response

We appreciate the commenter's suggestion. Under the proposed changes to § 2.51, an exception is allowed when normal policies and procedures for obtaining consent according to §§ 2.31 and 2.32 may not be operational due to a natural or major disaster. If the part 2 program is unable to obtain consent or provide services because the program is closed, then the part 2 program may disclose the records. We decline to explicitly name a safe-harbor provision, because the regulatory text describes the exception to the consent requirements. Immediately following disclosure, the part 2 program shall document, in writing, the disclosure in the patient's records, including the name of the medical personnel to whom the disclosure was made, their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the medical emergency.

Public Comments

One commenter stated that waiting for a bona fide emergency to allow providers to share information may be too late for the patient's care and that treating providers should be able to share information for safe care. One commenter noted that if a part 2 program is closed, then they may not be able to disclose information.

SAMHSA Response

Providers may share treatment information with other providers with patient consent at any time. However, we do not have the authority to permit information to be disclosed without patient consent prior to the medical emergency under the authorizing statute at 42 U.S.C. 290dd–2(b)(2)(A). Therefore, providers may not share information without patient consent prior to the declaration of a state of emergency and prior to a part 2 program closing due to the disaster unless the program meets another exception in this part.

J. Research (§ 2.52)

In response to comments received, SAMHSA is finalizing this section as proposed except for the proposed change allowing research disclosures to members of the workforce of a HIPAA covered entity.

SAMHSA recognizes the need for researchers to use SUD-related data to advance scientific research, particularly in light of the national opioid epidemic. SAMHSA supports the conduct of scientific research on SUD care, and has worked to allow researchers appropriate access to healthcare data relating to SUD, while maintaining appropriate confidentiality protections for patients.

Under 42 CFR 2.52, part 2 programs are permitted to disclose patient identifying information for research, without patient consent, under limited circumstances. In the 2017 Final Rule, SAMHSA made several changes to the research exception at § 2.52, including permitting the disclosure of data by lawful holders (as well as by part 2 programs) to qualified personnel for the purpose of conducting scientific research.

As stated in the 2019 proposed rule (84 FR 44577), § 2.52 allows the disclosure of patient identifying information for research purposes without patient consent, if the recipient of the patient identifying information is a HIPAA-covered entity or business associate, and has obtained and documented authorization from the patient, or a waiver or alteration of authorization, consistent with the HIPAA Privacy Rule at 45 CFR 164.508 or 164.512(i) or the recipient is subject to the HHS regulations regarding the protection of human subjects under the Common Rule. (45 CFR part 46).

Since the 2017 Final Rule, SAMHSA has become aware that limiting research disclosures under § 2.52, to only HIPAA-covered entities or institutions subject to the Common Rule,[16] may make it more difficult for some legitimate stakeholders to obtain data from SUD treatment records, for the purpose of conducting scientific research. For example, under the provisions of § 2.52, the disclosure by a lawful holder of SUD records for the purpose of research to a state agency without a part 2 patient consent may be barred, given that most state agencies are neither HIPAA-covered entities nor directly subject to the Common Rule. It

[16] The Common Rule governs research conducted or supported (*i.e.,* funded) by the 16 departments and agencies that issued the Common Rule.

is not SAMHSA's intention or policy to make it more burdensome for these sorts of stakeholders to carry out scientific research. SAMHSA would like to more closely align the requirements of 42 CFR 2.52 (disclosures for the purpose of research), with the currently analogous provisions on research under the HIPAA Privacy Rule (45 CFR 164.512(i)) and the Common Rule, in order to minimize any conflict or duplication in the requirements for consent to disclosure of records for the purpose of research. Therefore, SAMHSA proposed to modify the text of § 2.52(a), in order to allow research disclosures of part 2 data from a HIPAA covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule, provided that any such data will be disclosed in accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i). This change will align the requirements of part 2 with the Privacy Rule around the conduct of research on human subjects. SAMHSA stated in the proposed rule that we believe this change to § 2.52(a) is needed, in order to allow an appropriate range of stakeholders to conduct scientific and public health research on SUD care and SUD populations.

In addition, SAMHSA proposed two additional changes to the text of § 2.52(a). First, SAMHSA proposed to add new § 2.52(a)(1)(iii), in order to clarify that research disclosures may be made to members of the workforce of a HIPAA-covered entity for purposes of employer-sponsored research, where that covered entity requires all research activities carried out by its workforce to meet the requirements of either the Privacy Rule and/or Common Rule, as applicable. Second, SAMHSA proposed to add new § 2.52(a)(1)(iv), to permit research disclosures to recipients who are covered by FDA regulations for the protection of human subjects in clinical investigations (at 21 CFR parts 50 and 56), subject to appropriate documentation of compliance with FDA regulatory requirements, and pursuant to authority under the Federal Food, Drug, and Cosmetic Act. In both instances, these proposals would help to align the part 2 requirements for research disclosures of SUD data, with analogous requirements for the conduct of research on human subjects that may apply under other federal regulations in specific circumstances.

The comments we received on the proposed amendments to § 2.52 and our responses are provided below.

Public Comments

Many commenters supported the proposal to broaden part 2 disclosures for research purposes to include entities not covered by HIPAA or the Common Rule so long as the part 2 data is disclosed in accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i).

SAMHSA Response

We thank commenters for their support.

Public Comments

Several commenters opposed the proposal. A few commenters felt that patient consent should be obtained before disclosing part 2 information for research purposes to entities not covered by HIPAA or the Common Rule. A few commenters felt that the proposed change will result in additional legal prosecution and discrimination. One commenter noted that it may make it difficult to identify a breach. One commenter recommended that SAMHSA clarify what level of protections non-HIPAA covered entities will be held to when part 2 data is disclosed for research purposes. The commenter suggested that sharing sensitive data with non-HIPAA covered entities should require IRB approval and if this is not possible then only the minimal amount of identifiable information as possible.

SAMHSA Response

We are seeking a balance between protecting the confidentiality of SUD patient records and ensuring that researchers can conduct critical research on SUD care and SUD populations. The proposed change to § 2.52 would align the requirements of part 2 around the conduct of research on human subjects with the HIPAA Privacy Rule, the Common Rule and other analogous requirements for the conduct of research on human subjects that may apply under other federal regulations. Specifically, part 2 data may be disclosed from a HIPAA-covered entity or business associate to individuals and organizations who are neither HIPAA-covered entities, nor subject to the Common Rule, provided that any such data will be disclosed in accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i). The HIPAA Privacy Rule at 45 CFR 164.512(i) defines the requirements entities must fulfill to use protected health information for research. This includes requirements that the research must be conducted under review of an Institutional Review Board (IRB) or a privacy board with members of varying backgrounds and appropriate professional competency. For the IRB or privacy board to approve a waiver of individual authorization, researchers must show that the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals and include an adequate plan to protect the identifiers from improper use and disclosure, an adequate plan to destroy the identifiers at the earliest opportunity, and consistent and adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity. We further note that the research provision (§ 2.52(b)) already includes a requirement that the researcher receiving the part 2 data is fully bound by 42 CFR part 2. We are interested in affording patients protected by 42 CFR part 2 the same opportunity to benefit from research, including research conducted by non-covered entities, while continuing to safeguard their privacy.

Public Comments

One commenter recommended that SAMHSA develop FAQs or guidance to ensure that entities that are not HIPAA-covered entities under HIPAA but who are making disclosures in accordance with the HIPAA Privacy Rule understand their obligations and responsibilities.

SAMHSA Response

We thank the commenter for their suggestion. We note that at the time of the publication of the proposed rule, we published a Fact Sheet, providing a general overview of the proposed rule, available here: *https://www.hhs.gov/about/news/2019/08/22/hhs-42-cfr-part-2-proposed-rule-fact-sheet.html.* We will consider updating subregulatory guidance, as applicable, to include any revisions made in the Final Rule. We will also consider issuing additional subregulatory guidance, as necessary.

Public Comments

One commenter recommended that SAMHSA clarify how the part 2 EHR system should identify characteristics to whom data is sent to including entities that receive data for research purposes. The commenter recommended referencing standards that support conveying these characteristics.

SAMHSA Response

We appreciate the commenter's recommendations. We will evaluate the commenter's suggestions and will consider options to provide technical guidance, including working with ONC and other stakeholders.

Public Comments

One commenter noted that the provisions which facilitate the release of data for research purposes do not necessarily permit disclosure for public health analysis and may not satisfy the requirements of the research exemption. A few commenters recommended including a provision that would explicitly allow the release of data to a state or state data repository if the state agency is authorized by state law to collect such information for the purpose of public health research.

SAMHSA Response

Under our revisions, a part 2 program or other lawful holder of part 2 data is authorized to disclose part 2 data for research purposes, including to state agencies, provided that the disclosure is made in accordance with the HIPAA Privacy Rule requirements at 45 CFR 164.512(i). Broadening the research exception further is beyond the scope of the current rulemaking activities. Note, however, that the CARES Act specifically permits disclosures of de-identified data to a public health authority whether or not a patient gives written consent. HHS anticipates future rulemaking to implement § 3221 of the CARES Act.

Public Comments

One commenter recommended that SAMHSA require that data released should be de-identified and that SAMHSA should define a rigorous process for de-identification.

SAMHSA Response

We encourage the use of de-identified or non-identifiable information whenever possible. However, it may be time consuming, labor intensive, or technologically difficult for part 2 programs to create data that does not contain part 2 identifying information. It may be too cumbersome or cost prohibitive for part 2 programs to provide the kind of data necessary in a de-identified format. The proposed changes will require that data is disclosed in accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i), such that researchers from covered entities and non-covered entities, must show that ''the research could not practicably be conducted without access to and use of the protected health information.'' Compliance with HIPAA and the Common Rule (*e.g.,* IRB and/or privacy board review), as required under existing regulations and the proposed changes to § 2.52, provide sufficient assurances of patient confidentiality, including that the researcher has a plan to protect and destroy identifiers and to not re-disclose the information in an unauthorized manner.

Public Comments

One commenter recommended that SAMHSA modify the proposal to address the rare situation when the holder of the part 2 data is not subject to HIPAA.

SAMHSA Response

We appreciate the commenter's suggestion. The revised research exception will permit disclosures of part 2 data for research purposes if the part 2 program or other lawful holder of part 2 data is a HIPAA-covered entity or business associate and the disclosure is made in accordance with the HIPAA Privacy Rule. Because we are expanding the authority of research disclosures beyond HIPAA-covered entities or entities covered by the Common Rule, we believe it is necessary to ensure that those disclosing the data are familiar with the HIPAA Privacy Rule and the requirements included in the regulations. We agree with the commenter that it will likely be a rare situation when the holder of the part 2 data is not subject to HIPAA and we do not anticipate that it will hinder most research efforts. However, we will consider it for any potential future rulemaking.

Public Comments

One commenter recommended that SAMHSA more closely align with HIPAA and suggested removing language that directs an ''individual designated as director or managing director, or individual otherwise vested with authority to act as chief executive officer or their designee'' to make a determination regarding the permissibility of research disclosures.

SAMHSA Response

We thank the commenter for the suggestion. Revising the language in this section is beyond the scope of the current rulemaking activities; however, we will evaluate the commenter's suggestion and consider potential options including future rulemaking.

Public Comments

One commenter noted that the proposed change exceeds the language or the purpose of the enabling statute.

SAMHSA Response

Under 42 U.S.C. 290dd–2(b)(2)(B), the content of an SUD treatment record may be disclosed without patient consent to qualified personnel for the purpose of conducting scientific research provided that such personnel does not identify, directly or indirectly, any individual patient in any report of such research; thus, we believe that this change does not violate the language of the enabling statute.

Public Comments

Several commenters opposed the proposal to permit research disclosures to members of the workforce of a HIPAA-covered entity for purposes of employer-sponsored research. The commenters noted that the proposal may lead to employment discrimination for those with SUD if data is released for purposes of employer-sponsored research. One commenter noted that it is unclear what ''employer-sponsored'' research would include.

SAMHSA Response

We proposed to allow part 2 data to be disclosed for research purposes to a member of the workforce of a HIPAA-covered entity. The proposal would clarify that the lawful holder of part 2 data may disclose the data to a member of the workforce of a HIPAA-covered entity provided that the research is being conducted at the direction or on behalf of that individual's employer. The proposed revisions would only permit this disclosure when the employer requires that all research conducted at the direction or on behalf of the employer is conducted in accordance with the HIPAA Privacy Rule or the Common Rule. During the review of comments, we noted that a few commenters misinterpreted ''employer-sponsored research'' to include research conducted by employers on or about their employees. It was not our intent to permit employers to conduct SUD research on their employees. Given the concerns and the confusion regarding the proposed changes, we are not finalizing this policy at this time. To reflect this in this final rule, the regulation text proposed at § 2.52(a)(1)(iii) is not being finalized and the regulation text proposed at §§ 2.52(a)(1)(iv) and (v) are being redesignated as §§ 2.52(a)(1)(iii) and (iv), respectively.

Public Comments

A few commenters supported the proposal to permit disclosures to members of the workforce of a HIPAA-covered entity for purposes of employer-sponsored research, where that covered entity requires all research activities carried out by its workforce to meet the requirements of either the Privacy Rule and/or Common Rule, as applicable.

SAMHSA Response

We thank commenters for their support. While we are not finalizing the policy at this time, research disclosures of part 2 data may still be made following the requirements at § 2.52(a).

Public Comments

A few commenters supported the proposal to permit research disclosures to recipients who are covered by FDA regulations for the protection of human subjects in clinical investigations.

SAMHSA Response

We thank commenters for their support.

Public Comments

A few commenters opposed the proposal to permit research disclosures to recipients who are covered by FDA regulations. One commenter stated that a patient's informed consent should be sought when disclosing information for research.

SAMHSA Response

The proposed changes will help align research disclosure requirements among other federal regulations. Allowing research disclosures to recipients who are covered by FDA regulations for the protection of human subjects will help facilitate critical research on SUD treatment and care. We believe it is necessary to strike a balance of promoting research while maintaining confidentiality for patient records. Like the HIPAA Privacy Rule, the FDA regulatory requirements generally require informed consent, except in limited circumstances as explained in 21 CFR part 50. The proposed changes require that the research is in compliance with the requirements of the FDA regulations, including review by an IRB when applicable.

K. Audit and Evaluation (§ 2.53)

In response to comments received, SAMHSA, in § 2.53(c)(1), is removing the expectation that certain audits and evaluations conducted by government agencies and third-party payers would only be conducted periodically, and is making changes to the language in (c)(1)(i)–(iii) to clarify SAMHSA's intent that revisions are intended to help enhance patient care and coverage. SAMHSA is also making several non-substantive changes to the proposed regulatory text of § 2.53, such as updating cross references to other sections of the rule and re-wording and moving the placement of language related to audits conducted by entities that have direct administrative control over a part 2 program.

SAMHSA is finalizing the proposal to permit disclosure of patient identifying information to federal, state, or local government agencies, and to their contractors, subcontractors, and legal representatives for audit and evaluations required by statute or regulation.

Regulations at §§ 2.53(a), (b), and (c) describe the circumstances under which specified individuals and entities may access patient identifying information in the course of an audit or evaluation. Section 2.53(a) governs the disclosure of patient identifying information for audits and evaluations that do not involve the downloading, forwarding, copying, or removing of records from the premises of a part 2 program or other lawful holder. In these instances, information may be disclosed to individuals and entities who agree in writing to comply with the limitations on disclosure and use in § 2.53(d) and who perform the audit or evaluation on behalf of one of the following: A federal, state, or local governmental agency that provides financial assistance to or is authorized to regulate a part 2 program or other lawful holder; an individual or entity which provides financial assistance to a part 2 program or other lawful holder; a third-party payer covering patients in a part 2 program; or a quality improvement organization (QIO) performing certain types of reviews. The regulations permit disclosure to contractors, subcontractors, or legal representatives performing audits and evaluations on behalf of certain individuals, entities, third-party payers, and QIOs described directly above. At § 2.53(a)(2), the regulations also allow part 2 programs or other lawful holders to determine that other individuals and entities are qualified to conduct an audit or evaluation of the part 2 program or other lawful holder. In these instances, patient information may be disclosed during an on-premises review of records, as long as the individuals and entities agree in writing to comply with the limitations on disclosure and use in § 2.53(d).

Section 2.53(b) of the regulation governs the copying, removing, downloading, or forwarding of patient records in connection with an audit or evaluation performed on behalf of government agencies, individuals, and entities described in 42 CFR 2.53(b)(2), which are identical to the agencies, individuals, and entities described in § 2.53(a)(1) above. In these audits, records containing patient identifying information may be copied or removed from the premises of a part 2 program or other lawful holder, or downloaded or forwarded to another electronic system or device from the part 2 program's or other lawful holder's electronic records, by an individual or entity who agrees to the records maintenance standards and disclosure limitations outlined in § 2.53(b)(1)(i) through (iii).

Additionally, patient identifying information may be disclosed to individuals and entities who conduct Medicare, Medicaid, or CHIP audits or evaluations as set forth in § 2.53(c).

SAMHSA understands there is confusion about § 2.53 as it applies to several specific situations, and therefore proposed to make the following changes to the regulations to improve clarity about what is permissible under these sections. SAMHSA also proposed to update part 2 regulatory language related to quality improvement organizations (QIO) to align with 42 CFR 476.1. Specifically, we proposed to replace references to ''utilization or quality control review'' with the term ''QIO review,'' which is defined in 42 CFR 476.1 as a review performed in fulfillment of a contract with CMS, either by the QIO or its subcontractors.

First, some stakeholders have voiced frustration that part 2 programs have been unwilling or unable to disclose patient records that may be needed by federal, state, and local agencies, to better serve and protect patients with SUD. For example, a state Medicaid Agency or state or local health department may need to know about specific types of challenges faced by patients receiving opioid therapy treatment, such as co-occurring medical or psychiatric conditions, or social and economic factors that impede treatment or recovery. An agency may need this kind of information to recommend or mandate improved medical care approaches; to target limited resources more effectively to care for patients; or to adjust specific Medicaid or other program policies or processes related to payment or coverage to facilitate adequate coverage and payment. Government agencies may also wish to know how many patients test positive for a new and harmful illicit drug, and how part 2 programs are actually treating those patients, as an input to agency decisions aimed at improving quality of care. For example, agencies may wish to modify requirements for part 2 programs, educate or provide additional oversight of part 2 providers, and/or update corresponding payment or coverage policies. Third-party payers covering patients in a part 2 program may have similar objectives for obtaining part 2 information.

Current regulations allow part 2 programs to share information for the purposes described above in two ways, using either de-identified or identifiable information. Only SUD records containing patient identifying information are subject to part 2 protections, and therefore a part 2 program or other lawful holder may share non-identifiable information with government agencies (federal, state and local) for many types of activities.

SAMHSA encourages the use of de-identified or non-identifiable information whenever possible. However, it may be time consuming, labor intensive, or technologically difficult for part 2 programs to create, and for government agencies to obtain quickly, data that does not contain part 2 identifying information. It may be too cumbersome or cost prohibitive for part 2 programs to provide the kind of data necessary in a de-identified format. It also may be challenging for part 2 programs to provide information quickly in more urgent situations, without potentially diverting resources away from patient care.

Patient identifying information may also be used to help agencies and third-party payers improve care in certain circumstances. Under current regulations at § 2.53(a) and (b), federal, state, and local government agencies that have the authority to regulate or that provide financial assistance to part 2 programs, and third-party payers with covered patients in part 2 programs, may receive patient identifying information in the course of conducting audits or evaluations. Additionally, patient identifying information may be disclosed to individuals and entities to conduct Medicare, Medicaid, or CHIP audits or evaluations under § 2.53(c). Thus, a Medicaid agency may evaluate the part 2 providers that participate in its Medicaid program; a state health department may audit the facilities it licenses pursuant to its regulatory authority; and a health plan may review part 2 programs that serve its enrollees.

The current regulations do not define audit and evaluation, nor do they direct the manner in which evaluations are carried out, as noted by § 2.2(b)(2). Nevertheless, we stated in the proposed rule that we believe that the concept of audit or evaluation is not restricted to reviews that examine individual part 2 program performance. We specifically said they may also include periodic reviews of part 2 programs to determine if there are any needed actions at an agency level to improve care and outcomes across the individual part 2 programs the agency regulates or supports financially. Likewise, we noted that audits or evaluations may include reviews to determine if there are needed actions at a health plan level to improve care and outcomes for covered patients in part 2 programs. In other words, audits or evaluations may be conducted with a goal to identify additional steps agencies or third-party payers should be taking to support the part 2 programs and their patients. This includes reviews that allow agencies or third-party payer entities to identify larger trends across part 2 programs, in order to respond to emerging areas of need in ways that improve part 2 program performance and patient outcomes.

SAMHSA proposed to clarify that under § 2.53, government agencies and third-party payer entities would be permitted to obtain part 2 records without written patient consent to periodically conduct audits or evaluations for purposes such as identifying agency or health plan actions or policy changes aimed at improving care and outcomes for part 2 patients (*e.g.,* provider education, recommending or requiring improved health care approaches); targeting limited resources more effectively to better care for patients; or adjusting specific Medicaid or other insurance components to facilitate adequate coverage and payment. These agencies and third-party payers are required to abide by the restrictions on disclosure and other relevant confidentiality requirements outlined in § 2.53. Additionally, SAMHSA stated in the proposed rule that it did not believe it was generally necessary to conduct these types of audits or evaluations on a routine or ongoing basis. Rather, we stated that we would generally expect that they would be performed periodically, unless they are required by applicable law or other compelling circumstances exist, such as unique cases in which an oversight agency determines there is a need for ongoing review. We also stated that information disclosed for the purpose of a program audit or evaluation may not be used to directly provide or support care coordination. As stated previously (83 FR 243), SAMHSA believes it is important to maintain patient choice in disclosing information to health care providers with whom patients have direct contact. Agencies or health plans could, for example, use information from the aggregated results of part 2 program evaluations to determine that a new benefit or payment category is needed in order to facilitate better care coordination.

The preamble to the 2017 final rule noted that the authorizing statute for part 2 does not provide a general exception to the consent requirement for disclosure of SUD records for the purpose of sharing records with public health officials (82 FR 6079). Furthermore, the preamble also noted that SAMHSA does not have the statutory authority to authorize routine disclosure of part 2 information for public health purposes (82 FR 6079). In the 2019 proposed rule, SAMHSA emphasized that audits or evaluations using aggregated data for such purposes described above are distinct from a broader public health exception. Specifically, under current regulations, part 2 programs may share information with the agencies that have the authority to regulate or provide financial support to the part 2 program, in order to safeguard or improve the care and outcomes for current and future patients in those programs, or to ensure the integrity of the funding program and the appropriate use of financial support by the part 2 program. A broader public health exception would conceivably enable part 2 programs to share identifiable information with any public health agency, regardless of its relationship with the part 2 program, for many types of purposes (*e.g.,* preventative efforts aimed at a wider population).

To clarify allowable program evaluation activities using patient identifying information, SAMHSA proposed several changes to § 2.53. First, SAMHSA proposed to redesignate current § 2.53(c) and (d) as § 2.53(e) and (f), respectively, and insert a new § 2.53(c) titled: ''*Activities Included.*'' Proposed new paragraph § 2.53(c)(1) specified that audits or evaluations may include periodic activities to identify actions that an agency or third-party payer entity can make, such as changing its policies or procedures to improve patient care and outcomes across part 2 programs; targeting limited resources more effectively; or determining the need for adjustments to payment policies for the care of patients with SUD. This change was intended to clarify that disclosures of patient records by a part 2 program to an agency or third-party payer entity are permitted for these purposes without patient consent, pursuant to this section.

Second, SAMHSA noted in the proposed rule (84 FR 44579) that it has received feedback that stakeholders are unclear about whether § 2.53 allows federal, state, and local government agencies and third-party payers to have access to patient information for activities related to reviews of appropriateness of medical care, medical necessity, and utilization of services. As described above, the

current regulations allow information to be disclosed to certain federal, state, and local governmental agencies and third-party payers for audit or evaluation purposes, as long as they agree to specific restrictions outlined in the regulations to limit disclosure or use of the records and preserve patient confidentiality. While neither the statute nor the regulations define audit or evaluation, we stated that these terms should and do include audits or evaluations to review whether patients are receiving appropriate services in the appropriate setting. Assessing whether a part 2 program provides appropriate care is a necessary part of any comprehensive part 2 program audit or evaluation. Government agencies may be charged with conducting such reviews for licensing or certification purposes or to ensure compliance with federal or state laws, as may private not-for-profit entities granted authority under the applicable statutes or regulations to carry out such work in lieu of the agencies. Third-party payers also have a stake in the programmatic integrity, as well as the clinical quality, of the part 2 programs that serve the patients they cover. Therefore, SAMHSA proposed to insert a new § 2.53(c)(2) that clarifies audit and evaluations under this section may include, but are not limited to, reviews of appropriateness of medical care, medical necessity, and utilization of services. Stakeholders were also referred to § 2.33, which allows disclosure of information for payment and/or health care operations activities with a patient's consent.

Third, we explained that stakeholders have expressed confusion about whether part 2 programs may disclose information for audit or evaluation purposes to the larger health care organizations in which they operate. For example, Medicare Conditions of Participation regulations at 42 CFR 482.21 require individual hospitals to conduct quality assessment and performance improvement (QAPI) programs that reflect the complexity of each hospital's organization and services, and which involve all hospital departments and services. QAPI programs are ongoing, hospital-wide, data-driven efforts that focus on addressing high-risk, high-volume or problem prone areas that affect health outcomes, patient safety, or quality of care.

As we noted in the proposed rule (84 FR 44580), the part 2 regulations provide ample leeway for part 2 programs to share information within their larger health care organizations for these and other types of evaluations. Under § 2.53(a)(2), part 2 programs may determine that individuals or entities within their health care organizations are qualified to conduct audits and evaluations and may share information pursuant to such reviews. Additionally, § 2.12(c)(3) states that, ''*The restrictions on disclosure in the regulations in this part do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients with substance use disorders if the communications are:*

(i) Within a part 2 program; or

(ii) Between a part 2 program and an entity that has direct administrative control over the program.'' The phrase ''direct administrative control'' refers to the situation in which a substance use disorder unit is a component of a larger behavioral health program or of a general health program.

In order to eliminate any remaining misunderstanding, however, SAMHSA proposed to expand the regulatory language to explicitly clarify that this type of information sharing is permitted under the regulations. Specifically, we proposed to add language to § 2.53(a)(2) to state that, ''Auditors may include any non-part 2 entity that has direct administrative control over the part 2 program or lawful holder.'' Additionally. SAMHSA proposed to include similar language in new subsection (b)(2)(iii). We stated that we believed that the proposed changes will help to clarify that in these situations, identifiable patient diagnosis or treatment information can be shared with personnel from an entity with direct administrative control over the part 2 program, where those persons, in connection with their audit or evaluation duties, need to know the information.

Fourth, while the regulations at § 2.53(a)(1)(ii) and (b)(2)(ii) specifically delineate that information may be disclosed to quality improvement organizations, these provisions do not explicitly include other types of entities that are responsible for quality assurance. For example, the regulations for audit and evaluation do not describe entities, such as health care organization accrediting or certification bodies, that may need to review patient records to evaluate whether a part 2 program meets quality and safety standards. To ensure that stakeholders understand that disclosure to these types of organizations is permitted, SAMHSA proposed to insert a new § 2.53(d) stating, ''Quality Assurance Entities Included. Entities conducting audits or evaluations in accordance with § 2.53(a) and (b) may include accreditation or similar types of organizations focused on quality assurance.''

Additionally, at the time the NPRM was published, SAMHSA understood that some federal, state, and local government agencies face challenges in meeting statutory or regulatory mandates that require them to conduct audits or evaluations involving part 2 information. For example, the Centers for Medicare & Medicaid Services conducts risk adjustment and data validation in connection with the risk adjustment program it is required to operate in accordance with section 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18063 and implementing regulations. Under risk adjustment data validation, health insurance issuers are lawful holders of part 2 identifying information and may be required to provide it to CMS or its contractors. Therefore, SAMHSA proposed to insert a new § 2.53(g) to permit patient identifying information to be disclosed to federal, state, and local government agencies, as well as their contractors, subcontractors, and legal representatives of such agencies, in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using de-identified information.

In addition to these changes, SAMHSA proposed to update language related to quality improvement organizations. At § 2.53(a)(1)(ii) and (b)(2)(ii), it proposed to amend the language to align it with 42 CFR 476.1. Specifically, SAMHSA proposed to replace references to ''utilization or quality control review'' with the term ''QIO review.''

The comments we received on the proposed amendments to § 2.53 and our responses are provided below.

Public Comments About the Proposals for Audit and Evaluation in General

Public Comments

Several commenters expressed support for the audit and evaluation proposals in general, saying clarification of these provisions can help decrease confusion and administrative burden, particularly among prescribing practitioners and auditors who conduct inspection and evaluation activities. One commenter stated that the proposed changes would enable better evaluation of the entire SUD treatment system of care. Another emphasized that focused oversight will help measure the efficacy of new SUD-related health care benefits offered by government and commercial

programs, reinforcing public trust in such programs while ensuring that adequate funds are available for at-risk populations.

SAMHSA Response

We thank the commenters for their support.

Public Comments

Several commenters were critical of the changes. A few commenters expressed concern about expanded data sharing under the proposals, including with non-government and/or non-treatment actors, that could ultimately negate the current rule's privacy and consent protections.

SAMHSA Response

In this rule, SAMHSA is primarily clarifying activities that are already permissible under § 2.53. Except for new § 2.53(g), we do not interpret the changes as conferring new authority for expanded data sharing and do not believe the changes will undermine the rule's privacy and consent protections.

Public Comments

A few commenters expressed concern that activities under the proposed § 2.53(c)(1)(ii) and/or § 2.53(c)(2) could be used as a means to deny care and/or services to patients with a SUD, and one commenter recommended that SAMHSA provide additional examples of program activities to ensure that such activities are performed in accordance with the regulation. Another commenter said the proposed rule will effectively remove the treating provider from the process.

SAMHSA Response

The goal of our clarifications in § 2.53(c)(1)(ii) and (c)(2) is to ensure that appropriate individuals, agencies and entities may use audits and evaluations to identify opportunities to improve services to patients in part 2 programs, as well as to conduct customary oversight activities that have the ability to safeguard patients and ensure they receive the right care. Without these clarifications, government agencies and third-party payers may be reluctant to undertake certain activities that are important to the care and safety of patients receiving services in part 2 programs. However, as referenced below, SAMHSA is modifying the language at § 2.53(c)(1)(ii) to clarify that the intent of the changes is to enhance care for patients.

Public Comments

A few commenters raised the issue of providing safeguards to prevent release of individually identifiable information, especially when patient information is used by third parties. One commenter emphasized the importance of ensuring that legitimate contractors use de-identified data whenever possible and follow the part 2 protections.

SAMHSA Response

Section 2.53 includes numerous safeguards to protect patient identifying information. For example, patient identifying information disclosed under § 2.53(a) and (b) may be disclosed only back to the part 2 program or other lawful holder from which it was obtained, and may be used only to carry out an audit or evaluation purpose, or to investigate or prosecute criminal or other activities if authorized by a court order. Under § 2.53(b), individuals, agencies, and entities conducting offsite reviews must maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16. Additionally, § 2.13 requires that any disclosures made under the part 2 regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

Public Comments

A few commenters raised the question of how eligible individuals and organizations may access unredacted part 2 information for audits and evaluations under the provisions of the proposed rule, and one stated that the rule does not address the problem of providers who are unwilling to disclose part 2 information to lawful holders subject to state or federal audits, which creates consequences for organizations such as Medicare Advantage Plans. One commenter said there was no process to verify whether identifiable information is needed, emphasizing that patients' private information would be vulnerable to a mere assertion that identifiable information must be revealed. The commenter believes that due process is removed for patients and that the system is ripe for abuse. A commenter suggested that HHS could provide data-use agreements or a memorandum of understanding, or revise the regulation to require a part 2 program or lawful holder to provide part 2 information as necessary to another provider or lawful holder in order to respond to an audit. One commenter suggested that clarification on the specific types of third parties with the specific methods and procedures for obtaining consent would be beneficial.

SAMHSA Response

In this final rule, SAMHSA is clarifying permissible activities under § 2.53 to help clear up confusion about the sharing of patient identifying information for the purposes of audit and evaluation. SAMHSA does not have the statutory authority to require patient records to be disclosed to auditors or evaluators. Further, we decline to issue specific direction regarding the processes through which patient identifying information is disclosed by part 2 programs or lawful holders to auditors and evaluators, as we believe the facts surrounding individual requests for information may vary, and those discussions are better left to stakeholders with first-hand knowledge of each situation. Additionally, SAMHSA believes such questions are out of the scope of this final rule, as they were not addressed in the proposed rule. We will take the suggestion for the creation of data use agreements and/or memorandums of understanding under advisement for future guidance or rulemaking.

Public Comments

A commenter said the correct application of the term ''evaluation'' is particularly unclear and subject to different interpretations.

SAMHSA Response

As stated in the proposed rule (84 FR 165), the current regulations do not define audit and evaluation, nor do they direct the manner in which evaluations are carried out, as noted by § 2.2(b)(2). Nevertheless, SAMHSA believes that the concept of audit or evaluation would at least include reviews that examine individual part 2 program clinical and/or financial performance as well as reviews of part 2 programs to determine if there are any needed actions at an agency or payer level to improve care and outcomes across individual part 2 programs.

Public Comments

One commenter said that Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions permitting Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs and believes that part 2 information will be required to be disclosed. The commenter suggested that SAMHSA include drug management and utilization review programs as program evaluation disclosures that do not require consent for disclosure of part 2 information. Alternatively, the commenter

recommended that the regulations be amended to provide that public program beneficiaries are deemed to have consented to part 2 disclosures when the public program requires such disclosures.

SAMHSA Response

SAMHSA believes it is important to identify patients at risk for misuse or abuse of frequently abused drugs, and that sharing information for the purposes of drug utilization review would already be allowed under §§ 2.31 and 2.33 when a patient consents to sharing their information for payment and health care operations. In this final rule, we are also adopting new language at § 2.53(c)(2) to clarify that audits and evaluations of part 2 programs may include reviews of appropriateness of medical care, medical necessity, and utilization of services. We agree that part 2 programs would be permitted to share information with Part D sponsors seeking to identify at-risk patients who may be candidates for drug utilization programs under this section as well.

Comments on SAMHSA's Proposals To Clarify Permitted Activities of Government Agencies and Third-Party Payers (§ 2.53 (c)(1))

Public Comments

Several commenters expressed support for the proposed changes to clarify the permitted activities of government agencies and third-party payers, stating that they reduce confusion and ambiguity and will help in providing efficient and effective care. A few commenters appreciated the recognition in the proposed rule that state agencies have audit and evaluation responsibilities that necessitate the receipt of part 2-protected data. One commenter underscored that states have an urgent need to utilize every available analytic tool to address the opioid crisis facing our nation.

SAMHSA Response

We thank the commenters for their support.

Public Comments

Several commenters opposed the changes, expressing concerns about expanded sharing of highly sensitive information without patient consent and with few or no parameters, and stating that the audit and evaluation exception already provides a fairly comprehensive mechanism for entities to share information without the consent of the patient. A few believed the changes would permit greater disclosures of patient records without consent to entities not involved in direct patient care. One commenter said that the proposed rule does not describe how granular level information would be shared between agencies or with third-party payer entities in ways that would not disclose patient identities in any manner and still be useful. One commenter expressed concern that virtually every use will be deemed compelling. A few commenters said that the proposed language exceeds the part 2 statute and that there is no value in maintaining the existing rule without enforcement of it. A few commenters also expressed concern that the proposed changes would allow patient identifying information to be used to reduce care, dictate care, remove the treating provider from the care process, limit access, or make decisions about patient care solely on what can be found in the files through such reviews. Another commenter said that patient records can be inaccurate and are rarely a full reflection of who the person is or the myriad of factors that go into the care process. One commenter said that the proposal opens patients up for discrimination.

SAMHSA Response

As noted in the proposed rule, SAMHSA has heard from stakeholders that there is confusion about what types of activities are permissible under § 2.53. The goal of our clarifications in § 2.53(c)(1) is to ensure that the appropriate individuals, agencies and entities understand that they may use audits and evaluations to identify opportunities to improve services to patients in part 2 programs, including making changes to payment policies that could increase access to effective services and targeting resources more effectively. SAMHSA believes the changes in this section represent clarifications of permissible activities under current regulations. However, in response to concerns expressed above, we are amending the language of this section to help clarify that our intent is to help government agencies and third-party payers as they seek to enhance the care and treatment of patients with SUD. We also note that the regulations include numerous safeguards to help ensure the proper handling of patient identifying information disclosed for audit and evaluation purposes. For example, newly redesignated § 2.53(f) requires that patient identifying information disclosed under this section may be disclosed only back to the part 2 program or other lawful holder from which it was obtained, and may be used only to carry out an audit or evaluation purpose, or to investigate or prosecute criminal or other activities, as authorized by a court order. Under § 2.53(b), individuals, agencies, and entities conducting offsite reviews must maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16. Additionally, § 2.13 requires that any disclosures made under the part 2 regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

Public Comments

One commenter noted that the phrase ''across part 2 programs'' could be interpreted to mean that evaluations must study only the part 2 programs themselves, and recommended changing this language to ''to improve care and outcomes for patients with SUDs that are treated by part 2 programs.''

SAMHSA Response

We thank the commenter for this suggestion, and agree that ''across part 2 programs'' may be interpreted too narrowly. Therefore, in this final rule, SAMHSA has changed the wording in § 2.53(c)(1)(i) to incorporate the commenter's suggested language.

Public Comments

One commenter said the ongoing nature of some Medicaid and Medicaid managed care organization quality control activities may be precluded based on language in the proposed rule stating that these types of audit and evaluation activities should only be periodic in nature. The commenter recommend that SAMHSA remove the ''periodic'' restriction for entities with direct administrative control and third-party payers, allowing them to continue to be provided with the flexibility to make determinations regarding the appropriate frequency of audit and evaluation activities. Another commenter asked for clarification about allowing ''periodic'' but not ''routine'' or ''ongoing'' reviews, stating that meaningful audits or evaluations that could be appropriately considered ''periodic'' could also be described as ''routine'' or ''ongoing.''

SAMHSA Response

SAMHSA appreciates the insight provided by the commenters. In the proposed rule, SAMHSA sought to clarify that under § 2.53, government agencies and third-party payer entities would be permitted to obtain part 2 records without written patient consent to periodically conduct audits or evaluations for purposes such as identifying agency or health plan actions or policy changes aimed at

improving care and outcomes for part 2 patients; targeting limited resources more effectively to better care for patients; or adjusting specific Medicaid or other insurance components to facilitate adequate coverage and payment. SAMHSA emphasized in the proposed rule that it did not believe it was generally necessary to conduct these types of audits or evaluations on a routine or ongoing basis. It was not SAMHSA's intention to interrupt or otherwise alter established audit and evaluation programs that already adhere to a specific schedule. Based on the comments received, we do not believe the regulations should indicate the frequency with which the permissible activities outlined in § 2.53(c)(1) should occur. We believe determinations about how often information is disclosed for audits and evaluations of this nature are best left to stakeholders with first-hand knowledge of each specific situation. Therefore, the final regulation text at § 2.53(c)(1) will not include the word ''periodically.''

Public Comments

One commenter appreciated that SAMHSA believes that the concept of audit or evaluation includes evaluations to identify additional steps and policy changes aimed at improving care and outcomes for part 2 patients, but also supported a broader public health exception to enable part 2 programs to share identifiable information with a public health agency for these purposes. The commenter recommended that § 2.53 be amended to define audit and evaluation as activities to include those conducted by a public health agency authorized by law to conduct public health research and implement programs aimed at improving care and outcomes for part 2 patients.

SAMHSA Response

We thank the commenter for their support and underscore that although the part 2 authorizing statute does not include a broad public health exception to the consent requirements, government agencies that have the authority to regulate, or that financially support part 2 programs, may conduct audits and evaluations of those programs in an effort to ensure that current and future patients receive the best care possible.

Public Comments

One commenter encouraged SAMHSA to include a requirement that any third party acting on behalf of an agency or organization for audits or investigations be required to produce a copy of its contract with the agency or entity on whose behalf the investigative activities are being conducted, in order to ensure that the third party is legitimate and has the authority to conduct the audit or investigation. The commenter noted that it would be helpful for the entity being audited or investigated to have written assurance that the part 2-covered information can be disclosed and used for these purposes.

SAMHSA Response

We thank the commenter for this suggestion and will consider it for future rulemaking. We underscore the importance for part 2 programs to have processes in place to ensure information is shared appropriately with any contractors, subcontractors or legal representatives conducting audits and evaluations on behalf of the designated individuals, agencies, and entities outlined in § 2.53. SAMHSA encourages part 2 programs and third parties to consider using copies of these types of contracts as one way to help verify a third-party's legitimacy.

In response to comments discussed above, we are finalizing this section with changes. We are removing the word ''periodically'' from § 2.53(c)(1) and amending the language of § 2.53(c)(1)(ii) and (iii) to help clarify that our intent is to help government agencies and third-party payers as they seek to enhance the care and treatment of patients with SUD. Additionally, we are amending the wording in § 2.53(c)(1)(i) to replace the phrase ''across part 2 programs'' with the phrase ''to improve care and outcomes for patients with SUDs who are treated by part 2 programs.''

Public Comments on SAMHSA's Proposal To Clarify Activities Related to Appropriateness of Care, Medical Necessity, and Utilization of Services (§ 2.53(c)(2))

Public Comments

A few commenters supported the proposal, stating that it will support quality improvement and cost containment efforts on the part of third-party payers and resolve ambiguity, and describing it as an essential component that should be retained in final regulations. One commenter stated their understanding that the NPRM is aimed at clarifying which activities fall within the terms ''audit and evaluation'' and does not necessarily expand or increase the activities already allowed.

SAMHSA Response

We thank the commenters for their support.

Public Comments

Several commenters opposed or expressed concerns about the proposed change. A few commenters said it could jeopardize individual patient insurance coverage, benefits, and access to care; give third-party payers a more defined or interfering role in treatment decisions; and subject patients to criminalization or stigma. One commenter noted they saw no enforcement measures in place to protect patients. Another commenter suggested that the permitted activities could arguably be accomplished through health care operations activities already permitted under § 2.33(b), following patient consent. Other commenters said the proposal exceeded the part 2 authorizing statute and raised concerns about the security of the information, believing that somehow the information would become available to fraudulent individuals marketing the latest SUD miracle cure to patients and families. One commenter said that care coordination should be added to the list of permitted audit and evaluation activities which would involve communication for similar, if not even more beneficial, purposes.

SAMHSA Response

In this rule, SAMHSA is primarily clarifying activities that are already permissible under § 2.53. As stated in the proposed rule, SAMHSA believes the definition of audit and evaluation should and does include reviews to assess whether patients are receiving appropriate services in the appropriate setting. Assessing whether a part 2 program provides appropriate care is a necessary part of any comprehensive part 2 program audit or evaluation. With regard to security concerns, § 2.53 includes numerous safeguards to protect patient identifying information disclosed under § 2.53(c)(2). Section 2.53(b), for example, requires auditors and evaluators conducting reviews using information that has been copied, removed, downloaded or forwarded, to maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16. Under newly designated § 2.53(f), patient identifying information disclosed under this section may be disclosed only back to the part 2 program or other lawful holder from which it was obtained, and may be used only to carry out an audit or evaluation purpose, or to investigate or prosecute criminal or other activities if authorized by a court order. Additionally, § 2.13 requires that any disclosures made

under the part 2 regulations must be limited to that information which is necessary to carry out the purpose of the disclosure. We note that care coordination is addressed in other parts of this rule.

For the reasons stated above, we are finalizing these changes as proposed.

Public Comments on SAMHSA's Proposal Related to Entities With Direct Administrative Control of Part 2 Programs (§ 2.53(a)(iii) and (b)(iii))

Public Comments

A few commenters supported the proposed change. One commenter described the change as a welcomed clarification.

SAMHSA Responses

We thank the commenters for their support. SAMHSA is finalizing this proposal with minor changes. Specifically, SAMHSA is altering the placement and wording of the new language at § 2.53(a) to better align it with new language at § 2.53(b).

Public Comments on SAMHSA's Proposal Related to Entities That Provide Quality Assurance (§ 2.53(d))

Public Comments

One commenter appreciated the clarification of accrediting organizations (AOs) as entities conducting audits and evaluations under part 2, stating that it is critical for AOs to review part 2 records to ensure that OTPs are meeting certain quality and safety standards in the delivery of care to SUD patients.

SAMHSA Responses

We thank the commenter for their support. We are finalizing this change as proposed.

Public Comments on SAMHSA's Proposal Related to Audits and Evaluations Mandated by Statute or Regulation (§ 2.53(g))

Public Comments

A few commenters appreciated and supported these clarifications and encouraged SAMHSA to finalize them. One commenter suggested that the rules should be revised to apply this exception not just for audits and evaluations required by law, but for any mandated reporting or disclosure required by law.

SAMHSA Response

We thank the commenter for their support. While the part 2 authorizing statute includes an exception to the consent requirement for the purposes of conducting management and financial audits and program evaluations, it does not include such an exception for any type of mandated reporting or disclosure.

Public Comments

One commenter said the proposed rule change exceeds the authority in 42 U.S.C. 290dd–2 and should be removed. Another commenter expressed concern that the section would act as a catch-all for government agencies and their contractors, subcontractors, and legal representatives to have access to any information that they determine necessary if the state statute mandates the disclosure. The commenter believed this would give the government access to any information that it deems necessary, including managed care companies working as government contractors delivering care to state members. The commenter described the proposal as inconsistent with other portions of the regulations, without providing any specific details, and suggested that SAMHSA should further review the potential implications of this section.

SAMHSA Response

The audit and evaluation exception codified at 42 U.S.C. 290dd–2(B) permits disclosure for a wide range of audit and evaluation activities. We believe that the proposal to permit audit and evaluation by government agencies that are mandated by law is consistent with the authorizing statute and current § 2.53(a) and (b). Furthermore, redesignated § 2.53(f) reiterates that patient identifying information may only be used to carry out the purpose of the audit and evaluation. Moreover, § 2.13(a) prohibits the disclosure or use of patient identifying information in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Therefore, we are finalizing § 2.53(g) as proposed.

Public Comments on SAMHSA's Proposal Related To Updating QIO Language

Public Comments

One commenter supported SAMHSA's proposed rule change to align part 2 with current QIO regulations.

SAMHSA Response

We thank the commenter for their support, and we are finalizing our amendments to § 2.53 relating to QIOs as proposed.

L. Orders Authorizing the Use of Undercover Agents and Informants (§ 2.67)

SAMHSA is finalizing this section as proposed.

Under the 1975 final rule, the placement of undercover agents or informants in a part 2 program was largely prohibited, other than as specifically authorized by a court order for the purpose of investigating a part 2 program, or its agents or employees, for allegations of serious criminal misconduct. At the time the 1975 final rule was promulgated, it was noted that, although the use of undercover agents and informants in treatment programs was ordinarily to be avoided, there occasionally arise circumstances where their use may be justified (42 FR 27809). More narrowly, it was noted that the authorizing statute, by itself, did not forbid the use of undercover agents or informants, and that the express statutory prohibition against direct disclosure of patient records is nevertheless subject to the power of the courts to authorize such disclosures under 42 U.S.C. 290dd–2(b)(2)(C). Building on these statutory considerations, it was concluded that the power to regulate the placement of undercover agents and informants is limited, and that the importance of criminal investigation of part 2 programs offers a legitimate policy basis for allowing the placement of undercover agents or informants in such programs, given a showing of good cause in specific instances. As explained in the preamble to the 1975 final rule, experience has demonstrated that medical personnel, no matter how credentialed, can engage in the illicit sale of drugs on a large scale, and that the use of undercover agents and informants is normally the only effective means of securing evidence sufficient to support a successful prosecution in such instances. Based on over 40 years of experience since then, SAMHSA believes it is still the case that medical personnel sometimes engage in the illicit sale or transfer of drugs, and that a process for authorizing undercover agents is important to ensure the safety of patients in these part 2 programs.

Under the 1975 final rule, a 60-day time limitation with regard to the placement of undercover agents and informants in a part 2 program was imposed, with the opportunity for an applicant to seek an extension of the court order, for a total of up to 180 days (42 FR 27821). In the 1987 final rule, that period of placement for undercover agents and informants pursuant to a

court order was extended to 6 months. This policy limitation was codified at § 2.67(d)(2).

Based on consultation with DOJ, the current policy is burdensome on, and overly restrictive of, some ongoing investigations of part 2 programs. Specifically, DOJ has stated that a typical undercover operation can often last longer than 6 months, and that 12 months is a more realistic timeframe for such operations. Therefore, SAMHSA proposed to amend § 2.67(d)(2), to extend the period for court-ordered placement of an undercover agent or informant to 12 months, while authorizing courts to further extend a period of placement through a new court order (84 FR 55481).

In addition, DOJ has stated that the current regulation text is ambiguous regarding when the current 6-month, or, as finalized, 12-month period, should start and stop, in determining whether a court-order period of placement has elapsed. SAMHSA considered multiple policy options regarding the tolling of the time period for an undercover placement. We considered having the time period begin on the date of the issuance of the court order. Alternatively, SAMHSA also considered having the time period begin on the date of placement of the undercover agent or informant. In consultations with DOJ, SAMHSA has found that there is often a lag of time between the court order and the placement of the agent or informant, for many reasons. Therefore, starting the time period when the court order is issued could significantly curtail the length of time an agent or informant can be undercover at a part 2 program. Furthermore, starting the time period based on date of placement of the agent or informant would provide greater clarity and predictability to law enforcement about exactly how long an agent or informant is allowed to be in the field, since the agent or informant is aware of the date his or her placement began, but may not be aware of the date of the court order. Thus, SAMHSA proposed to amend § 2.67(d)(2), to clarify that the proposed 12-month time period starts when an undercover agent or informant is placed in the part 2 program (84 FR 55481).

The comments we received on the proposed amendments to § 2.67 and our responses are provided below.

Public Comments

Some commenters opposed the presence of undercover officers and informants in part 2 programs for any length of time, citing privacy concerns, treatment deterrence, ethical violations, and a violation of constitutional rights. Some commenters specifically stated this proposal would perpetuate stigma. One commenter noted that officers should not be allowed in part 2 programs without proper behavioral health training.

SAMHSA Response

The authorizing statute (42 U.S.C. 290dd–2) and the regulations promulgated thereunder (42 CFR part 2) contain various safeguards to ensure that court orders authorizing the use of undercover agents and informants are not misused. For example, there must be an application citing certain good cause criteria, a court order noting the good cause, and notice provided to the director of the program. Furthermore, no information obtained by an undercover agent or informant placed in a part 2 program under the court order may be used to investigate or prosecute any patient in connection with a criminal matter (42 CFR 2.67(d)). Thus, we believe the regulations strike the appropriate balance between protecting patients from criminal activities by employees of part 2 programs and safeguarding the confidentiality and rights of these same patients.

Public Comments

A few commenters noted that this proposal is particularly concerning given the simultaneous proposal by SAMHSA (at 84 FR 44568) to remove ''allegedly committed by the patient'' from § 2.63 of the regulations. These commenters argued that, coupled together, the changes would allow the regulations to become a tool of prosecution and not recovery.

SAMHSA Response

As noted above, the authorizing statute (42 U.S.C. 290dd–2) and the regulations promulgated thereunder (42 CFR part 2) contain various safeguards against misuse of these provisions. Further, § 2.13(a) of the regulations specifically provide that ''[t]he patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Any disclosure made under the regulations in this part must be limited to that information which is necessary to carry out the purpose of the disclosure.'' Thus, we believe that these changes will serve to protect patients from crimes committed in part 2 programs while still safeguarding their confidentiality.

Public Comments

Many commenters disagreed with extending the length of placement of a court-order for an undercover agent or informant from 6 to 12 months, stating that this proposal does not purport to improve care coordination or patient safety. These commenters believe that this proposal may be interpreted by patients and providers as evidence that they are not safe in SUD treatment and may further deter treatment, stating that, given the current nationwide opioid crisis, it is important that SAMHSA strike an appropriate balance and promote greater access to comprehensive and coordinated SUD treatment. Commenters also requested additional details or examples regarding why 12 months is necessary for placement, arguing that there is no evidence that the current policy is encumbering ongoing investigations of part 2 programs or that allowing undercover agents in part 2 programs would address the causes of the opioid crisis. Some commenters noted that this proposal is particularly harmful to individuals living in areas that are already heavily policed.

SAMHSA Response

We disagree that this proposal does not improve patient safety. As noted above, the intent of the regulations is to protect patients, and the regulations at § 2.13(a) provide safeguards to ensure that ''[t]he patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority.'' In some situations, in order to build a case of wrong-doing in a part 2 program or by an employee in such a program, evidence must be collected for more than 6 months. We believe that 12 months appropriately strikes a balance between ensuring the necessary time for informants and safeguarding the confidentiality of patients.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are generally required to provide a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement can be approved by the Office of Management and Budget (OMB) for review and approval. Currently, the information collection is approved under OMB Control No. 0930–0092. In order to

fairly evaluate whether changes to an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that SAMHSA solicit comment on the following issues: (a) Whether the information collection is necessary and useful to carry out the proper functions of the agency; (b) The accuracy of the agency's estimate of the information collection burden; (c) The quality, utility, and clarity of the information to be collected; and (d) recommendations to minimize the information collection burden on the affected public, including automated collection techniques. We solicited public comment in the proposed rule on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (84 FR 44581 through 44584).

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered in rule making. SAMHSA explicitly sought, and considered, public comment on our assumptions as they relate to the PRA requirements summarized in this section.

This final rule includes changes to information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, as defined under the PRA (5 CFR part 1320). Some of the provisions involve changes from the information collections set out in the previous regulations. Below, SAMHSA briefly discusses each finalized proposal and whether each includes changes to information collection requirements.

In section IV.B. of this final rule, SAMHSA is finalizing its proposal to modify the existing definition of ''Records'' in § 2.11 to conform with other finalized revisions in this final rule. See section IV.B. for further information about this finalized proposal. SAMHSA does not believe this finalized proposal will result in any change in collection of information requirements since unrecorded information is, by its nature, not collected.

In section IV.C. of this final rule, SAMHSA is finalizing amendments to § 2.12 to clarify in that section that non-part 2 entities may record SUD treatment about a patient in its own records without triggering part 2 provided that such providers are able to differentiate their records from those received from a part 2 program and part 2 records received from lawful holders. See section IV.C. for further information about this finalized proposal. As stated in that section, SAMHSA is finalizing new regulatory text to clarify existing policies; thus, SAMHSA is not finalizing any changes to any collection of information requirements. Furthermore, we believe that the clarification represents standard practice in many, if not all, part 2 programs and among other lawful holders. That is, non-part 2 entities are already either segregating or segmenting any SUD records received from a part 2 program or deciding not to do so, based on their standard operations. This finalized proposal will merely clarify that if the non-part 2 entity does, in fact, segregate or segment these records, the recording of information about a SUD and its treatment by a non-part 2 entity does not by itself render a medical record subject to the restrictions of 42 CFR part 2. Thus, SAMHSA does not believe this finalized proposal results in any changes in collection of information requirements.

In section IV.D. of this final rule, SAMHSA is finalizing amendments to § 2.31, to allow patients to consent to disclosure of their information to entities, without naming the specific individual receiving this information on behalf of a given entity. See section IV.D. for further information about this finalized proposal. This finalized proposal may result in providers needing to update their standard consent forms to allow for certain disclosures to such entities; that additional burden is discussed in the Regulatory Impact Analysis, below. SAMHSA believes this finalized proposal may result in part 2 program disclosing more information to certain entities. We discuss this additional burden, in total, with the additional collection of information requirements that may result from the finalized proposals in sections IV.J., and IV.K, below. This amendment is also anticipated to decrease burden on patients by removing barriers to sharing their own information in order to receive benefits, services, or treatment, but we do not have the data to quantify this reduction.

In section IV.E. of this final rule, SAMHSA is finalizing modifications to the language in § 2.32(a)(1), to remove the superfluous language that has contributed to confusion regarding the restrictions on re-disclosure. See section IV.E. for further information about this finalized proposal. Since part 2 providers are already required, upon disclosure, to provide a written statement notifying the recipient of the applicability of 42 CFR part 2 to any re-disclosure of the protected record, consistent with the prior revisions to part 2, including the 2017 final rule (82 FR 6106), SAMHSA does not believe this finalized modification of the language results in any changes in collection of information requirements.

In section IV.F. of this final rule, SAMHSA is finalizing with modification its proposal to specify in regulatory text an illustrative list of 17 permitted activities for the purpose of disclosures under § 2.33. SAMHSA is modifying the list of permitted activities to add to § 2.33 that disclosures for care coordination and case management, and disclosures for other payment and/or health care operations activities not expressly prohibited under this provision, are also permitted. See section IV.F. for further information about this finalized proposal. As noted in that section, SAMHSA has previously stated that most of these activities are permitted (83 FR 241); this language will only further clarify the previously finalized policy. Moreover with regard to the addition of care coordination and case management activities to § 2.33, SAMHSA does not believe that this finalized modification of the language will result in providers seeking additional consents to disclosure in the future, nor in any additional burden for providers with regard to documenting consents. Therefore, SAMHSA does not believe this finalized proposal results in any changes in collection of information requirements.

In section IV.G. of this final rule, SAMHSA is finalizing provisions to expand the scope of § 2.34(d) to make non-OTP providers with a treating provider relationship eligible to query a central registry with their patient's consent to determine whether a patient is already receiving treatment through a member program to prevent duplicative enrollments and prescriptions for methadone or buprenorphine, as well as to prevent any adverse effects with other prescribed medications. See section IV.G. for further information about this finalized proposal. Based on SAMHSA's research, the policies and procedures governing central registries vary widely by each state; in fact, many states do not have central registries in place. Because of this lack of information, it is not possible to estimate either the number of additional queries which central registries may receive as a result of this finalized proposal or the time or effort required to answer these queries. Therefore, it is difficult to estimate any additional collection of information requirements which may result from this finalized proposal. Instead, SAMHSA requested that central registries and providers that would query central registries provide comments on any additional

information collection requirements this finalized proposal would cause and any resulting burden. SAMHSA did not receive any comments that would improve estimates of this burden. However, this provision removes barriers and expands eligibility, without requiring non-OTP providers to query the central registry.

In section IV.H. of this final rule, SAMHSA is finalizing its proposal to add a new § 2.36 permitting part 2 programs to report any data for controlled substances dispensed or prescribed to patients to PDMPs, as required by the applicable state law. See section III.G. for further information about this finalized proposal. SAMHSA anticipates that this finalized proposal may result in additional burden for part 2 programs choosing to report to PDMPs in two ways. If a part 2 program chooses to report to a PDMP, the program will need to update its consent forms to request consent for disclosure to PDMPs. That burden is discussed in the Regulatory Impact Analysis, below. The second part of the finalized proposal permits part 2 programs to report any data for controlled substances dispensed to patients to PDMPs, as required by the applicable state law. To estimate the additional collection of information requirements associated with this finalized proposal, SAMHSA used the average number of opiate treatment admissions from SAMHSA's 2014–2016 Treatment Episode Data Set (TEDS) as the estimate of the number of clients treated on an annual basis by part 2 programs (531,965). Although not all programs would need to report this information under state law or may choose to do so, SAMHSA has used this number to be conservative and comprehensive of any future burden if states require reporting in the future. TEDS ''comprises data that are routinely collected by States in monitoring their individual substance abuse treatment systems. In general, facilities reporting TEDS data are those that receive State alcohol and/or drug agency funds (including Federal Block Grant funds) for the provision of substance abuse treatment.'' [17] Although TEDS does not represent all of the admissions to part 2 programs, as reporting varies by state, SAMHSA believes it represents the vast majority of admissions. Conservatively, we assumed that each of these clients would consent to the re-disclosure of their information to PDMPs and would be dispensed medication required to be reported to a PDMP. SAMHSA assumes that part 2 programs, based on other state and federal requirements, already are required to query PDMP databases; therefore, SAMHSA does not include registration and infrastructure costs in this estimate. For example, several states require medical directors of OTPs to query their respective state PDMPs at minimum intervals, including IN, MN, MI, ND, NC, RI, TN, VT, WA, and WV.[18] Based on discussions with providers, SAMHSA also estimates that, in addition to an initial update to the PDMP database for existing patients, the PDMP database would typically need to be accessed and updated quarterly for each patient, on average. Likewise, based on discussion with providers, SAMHSA believes accessing and reporting to the database would take approximately 2 minutes per patient, resulting in a total annual burden of 8 minutes (4 database accesses/updates × 2 minutes per access/update) or 0.133 hours annually per patient. For the labor costs associated with this activity, SAMHSA used the average wage rate of $24.01 [19] per hour for substance abuse, behavioral disorder, and mental health counselors (multiplied by two to account for benefits and overhead costs) to estimate a total burden in year 1 for the initial update of the PDMP database of $851,498 (531,965 clients × 2 minutes (0.033 hours) per access/update × $48.02/hour) and an annual burden in each year of $3,405,992 (531,965 clients × 0.133 hours × $48.02/hour). Therefore, we estimate that this finalized proposal will result in an additional cost of $4,085,489 ($851,498 + $3,405,992), as reflected in Table 1, below.

In section IV.I. of this final rule, SAMHSA is finalizing an addition to § 2.51 to allow disclosure of patient information during natural and major disasters. See section IV.I. for further information about this finalized proposal. Because this finalized proposal by its very nature does not require additional consent requirements or other paperwork, SAMHSA does not believe it will result in any changes in collection of information requirements. Providers, under their own policies and procedures or other laws, may need to keep track of the disclosures made, which, could require additional paperwork. Such requirements, however, are not discussed in this rule, nor does SAMHSA have any way of estimating them, as policies and procedures may vary across providers.

In section IV.J., and section IV.K. of this final rule, SAMHSA is finalizing changes with modifications to amend §§ 2.52 and 2.53 to allow or clarify the ability to make certain disclosures without patient consent. First, in section IV.J. of this final rule, SAMHSA is finalizing to modify the text of § 2.52(a) in order to allow research disclosures of part 2 data from a HIPAA-covered entity or business associate to individuals and organizations who are neither HIPA-covered entities, nor subject to the Common Rule, provided that any such data will be disclosed in accordance with the HIPAA Privacy Rule. See section IV.J. for further information about this finalized proposal. Second, SAMHSA is clarifying allowed disclosures for audit and evaluation purposes under § 2.53 for activities undertaken by a federal, state, or local governmental agency or third-party payer to identify needed actions to improve the delivery of care, to manage resources effectively to care for patients, and/or to determine the need for adjustments to payment policies to enhance care or coverage for patients with SUD. SAMHSA is also finalizing language to clarify that (1) audits and evaluations may include reviews of appropriateness of medical care, medical necessity, and utilization of services; (2) part 2 programs may disclose information, without consent, to non-part 2 entities that have direct administrative control over such part 2 programs; and (3) entities conducting audits or evaluations in accordance with § 2.53(a) and (b) may include accreditation or similar types of organizations focused on quality assurance. Further, SAMHSA is finalizing the proposal under § 2.53(g) to permit patient identifying information to be disclosed to government agencies in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using de-identified information. Finally, SAMHSA is finalizing updates to language related to QIOs. See section IV.K. for further information about these finalized proposals. As stated in that section, SAMHSA believes that the regulations already permit audits and evaluations for reviews of appropriateness of medical care, medical necessity, and utilization of services. Likewise, SAMHSA also believes that the current regulations permit disclosure to a non-part 2 entity with direct administrative control over a part 2 program and to accreditation

[17] *https://wwwdasis.samhsa.gov/webt/information.htm.*

[18] *https://www.pdmpassist.org/pdf/Resources/Use%20of%20PDMP%20data%20by%20opioid%20treatment%20programs.pdf.*

[19] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, May 2019, Substance Abuse, Behavioral Disorder, and Mental Health Counselors, Standard Occupations Classification code (21–1018) [*www.bls.gov/oes/current/oes_nat.htm*].

and similar organizations. Therefore, although SAMHSA is finalizing language to clarify any confusion that may exist, it believes that these activities are already permitted and that they will not, therefore, result in any new collection of information requirements or any other burden. It also believes updating the QIO language will not create new collection of information requirements or increase burden. As noted above, SAMHSA is also finalizing a provision to clarify that patient identifying information may be disclosed to government agencies and third-party payers to identify needed actions at the agency or payer level, although we are removing the expectation that these reviews would take place periodically due to ambiguity about that term and to avoid interfering with currently-established audit schedules. We are not revising our burden estimates as a result of this modification because the frequency of these reviews is unaffected by the change. Additionally, SAMHSA is adopting a new provision to allow patient identifying information to be shared with government agencies in the course of conducting audits or evaluations mandated by statute or regulation, if those audits and evaluations cannot be carried out using de-identified information. In section IV.D of this final rule, SAMHSA is also finalizing a proposal to allow disclosure to entities with patient consent. SAMHSA believes that the finalized proposals in sections IV.D., J, and K, may result in additional collection of information requirements, as part 2 programs may be asked to disclose information to agencies and entities as a result. Although SAMHSA is not able to anticipate the increase in these disclosures, to estimate the potential cost, we first estimated the number of potentially impacted part 2 programs based on the anticipated number of requests for a disclosure in a calendar year. SAMHSA used the average number of substance abuse treatment admissions from SAMHSA's 2014–2016 TEDS (1,658,732) as the number of patients treated annually by part 2 programs. SAMHSA then estimated that part 2 programs would need to disclose an average of 15 percent of these records (248,810) as a result of these finalized proposals. We then estimated that 10 percent or 24,881 (248,810 × 10%) of impacted records would be held by part 2 programs who would use paper records to comply with these requests for disclosure reports while the remaining 90% or 223,929 (248,810 × 90%) would use a health IT system. For part 2 programs using paper records, SAMHSA expects that a staff member would need to gather and aggregate the information from paper records, and manually track disclosures; for those part 2 programs with a health IT system, we expect records and tracking information would be available within the system.

SAMHSA assumed medical record technicians would be the staff with the primary responsibility for compiling the information for a list of disclosures from both paper records and health IT systems. The average hourly rate for medical record and health information technicians is $22.40.[20] In order to account for benefits and overhead costs associated with staff time, we multiplied the hourly wage rate by two for a total average hourly wage rate of $44.80. Absent any existing information on the amount of time associated with producing a list of disclosures, SAMHSA assumed it would take a medical record technician 4 hours, on average, to produce the information from paper records at a cost of $179.20 (4 hours × $44.80/hour) and 0.25 hours, on average, to produce information from a health IT system at a cost of $11.20 (0.25 hours × $44.80/hour). Finally, SAMHSA assumes that agencies will request that these disclosures be made on secure, online databases, and would not require notification via email or first class mail, thus resulting in no additional cost to transmit this information. Based on these assumptions, SAMHSA estimates that this finalized proposal will result in an additional cost of $6,966,680 {(24,881 requests × $179.20 per request) + (223,929 requests × $11.20 per request)}, as reflected in Table 1, below.

In section IV.L. of this final rule, SAMHSA is finalizing amendments to § 2.67 to extend the period for court-ordered placement of an undercover agent or informant to 12 months, while authorizing courts to further extend a period of placement through a new court order. In that section, SAMHSA is also finalizing changes to explicitly state when the 12- month period begins to run. See section IV.L. for further information about this finalized proposal. The requirements of the Paperwork Reduction Act do not apply ''During the conduct of a Federal criminal investigation or prosecution, or during the disposition of a particular criminal matter'' (5 CFR 1320.4(a)(1)), or to information collections by the federal judiciary or state courts (5 CFR 1320.3(a)).[21]

Below, SAMHSA summarizes the estimated cost of the change in collection of information requirements discussed above. Along with publication of this rule, SAMHSA will submit the information collection revisions associated with this rule to the Office of Management and Budget for approval. After receiving a final action, SAMHSA swill publish a notice in the **Federal Register** to inform the public.

TABLE 1: ANNUALIZED BURDEN ESTIMATES

	Annual number of respondents	Responses per respondent	Total responses	Hours per response	Total hourly burden	Hourly wage cost	Total hourly cost
§ 2.36	531,965	5	2,659,825	0.033	88,661	$48.02	$4,257,491
§§ 2.31, 2.52, 2.53 (Paper Records)	24,881	1	24,881	4	99,524	44.80	4,458,675
§§ 2.31, 2.52, 2.53 (Health IT Systems)	223,929	1	223,929	0.25	55,982	44.80	2,508,005
Total	780,775		2,908,633		244,167		11,224,171

[20] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, May 2019, Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians, All Other, Standard Occupations Classification code (29–2098) [*www.bls.gov/oes/current/oes_nat.htm*].

[21] Except, for this latter case, in the rare circumstance that those information collections are conducted or sponsored by an executive branch department (5 CFR 1320.3(a)).

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to update the Confidentiality of Substance Use Disorder Patient Records regulations at 42 CFR part 2 to respond to the emergence of the opioid crisis, with its catastrophic impact on patients and corresponding clinical and safety challenges for providers. The goal of this final rule is to clarify existing requirements in 42 CFR part 2 and reduce barriers to information sharing to ensure appropriate care and patient safety.

As noted in the tables below, SAMHSA believes that the finalized policies in this final rule will result in some near-term non-recurring and annual recurring financial burdens. We have weighed these potential burdens against the potential benefits, and believe, on balance, the potential benefits outweigh any potential costs. Specifically, the finalized proposals in this rule are meant to allow providers to better understand the needs of their patients by clarifying the requirements under part 2 and to break down barriers to information sharing among part 2 programs and other providers. SAMHSA believes this information sharing would benefit patients because both part 2 programs and other providers would be able to more fully understand the patient's health history and avoid dangerous and even lethal adverse drug events. In addition, these finalized proposals are also intended to protect and empower patients by giving them more control over their consent and control of their records, for example, by allowing them to consent to disclosure to entities, should they so choose. Furthermore, in drafting these finalized proposals, SAMHSA was cognizant of privacy concerns and specifically drafted these finalized proposals to protect the privacy of patients; for example, the finalized proposal regarding OTP provider disclosure to PDMPs requires the consent of the patient. SAMHSA believes that increasing patient safety and the empowerment of patients will lead to better health outcomes, therefore balancing any burdens discussed below and any remaining privacy concerns.

B. Overall Impact

SAMHSA has examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 (Reducing and Controlling Regulatory Costs). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. We have a conducted a regulatory impact analysis for this rule, which we present here.

As discussed in the regulatory impact analysis, we believe this final rule meets the necessary is a de-regulatory action because it eliminates some of the burdens of, and barriers to, SUD treatment record-keeping previously imposed by 42 CFR part 2. The goal of this final rule is to improve the coordination of care for persons with SUD by reducing administrative burdens related to maintenance of disclosures and patient records for downstream, non-part 2 providers. By facilitating care coordination in this way, we anticipate primary care and general medical providers will be more able and more willing to coordinate care for their patients with SUD, and by extension, that quality of care and safety outcomes in the context of the opioids epidemic will improve. This final rule also seeks to facilitate appropriate maintenance of SUD patient records and communications, as by clarifying that the rule for disclosing SUD treatment records in a ''medical emergency'' can also apply in natural and major disaster situations. Here again, the goal is de-regulatory, and will reduce the administrative burden for providers in disclosing SUD treatment records in appropriate situations, while also improving care coordination, access to care, and safety during medical emergencies. While we are unable to quantify the benefits related to access and quality of care as well as improved safety and health outcomes for patients with SUD, we believe them to be substantial and to outweigh any additional regulatory burden or economic impacts that may result from the policies finalized in this rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses (including independent contractors), nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. The final rule will allow patients to consent to disclosure of their information to entities; permit part 2 programs to report data for controlled substances dispensed to patients to PDMPs with patient consent; and allow part 2 programs to comply with disclosure requests from federal, state, or local governmental agencies, third-party payers and researchers. These finalized proposals will result in additional reporting burden as well as near-term non-recurring and annual recurring regulatory impacts to part 2 programs. As shown in Table 2 and as discussed in the Collection of Information Requirements (Section V), we estimate the average cost impact per substance abuse treatment admission for staff training, updates to consent forms, and disclosures to agencies will be $4.32 in year 1 ($7,168,135 ÷ 1,658,732 patients) and $4.20 in years 2 through 10 ($6,966,680 ÷ 1,658,732 patients). For opiate treatment patients, we also estimate the average cost impact for disclosure to PDMPs to be $8.00 per patient in year 1 ($4,257,491 ÷ 531,965 patients) and $6.40 in years 2 through 10 ($3,405,992 ÷ 531,965 patients). When this is added to the costs for staff training, updates to consent forms, and disclosures to agencies, the aggregate cost impact per opiate treatment admission is $12.32 in year 1 and $10.60 in years 2 through 10. While we are unable to determine how many part 2 programs qualify as small businesses based on the minimum threshold for small business size of $38.5 million

(*https://www.sba.gov/federal-contracting/contracting-guide/size-standards*), we believe that on a per-patient basis, this final rule will not significantly affect part 2 treatment programs of any size. SAMHSA has not prepared an analysis for the RFA because it has determined, and the Secretary certifies, that this final rule does not have a significant economic impact on a substantial number of small entities.

As further described in section V., above, when estimating the total costs associated with changes to the 42 CFR part 2 regulations, SAMHSA estimated costs related to collection of information for the finalized changes to §§ 2.31, 2.52, 2.53, and (new) 2.36. In addition, we estimate that there may be additional burden related to updating consent forms as a result of the finalized proposals in §§ 2.31 and (new) 2.36. In section IV.D. of this final rule, SAMHSA is finalizing its proposal to amend § 2.31 to allow patients to consent to disclosure of their information to entities, without naming the specific individual receiving this information on behalf of a given entity. In section IV.H. of this final rule, SAMHSA is finalizing its proposal to add a new § 2.36, permitting part 2 programs to report to PDMPs; patients must consent to disclosure before this reporting can occur. See sections IV.D. and IV.H. for further information about these finalized proposals. These finalized proposals may result in providers needing to update their standard consent forms to allow for certain disclosures. As stated in the 2016 proposed rule (81 FR 7009 through 7010), based from a 2008 study from the Mayo Clinic Health Care Systems,[22] the reported cost to update authorization forms was $0.10 per patient. Adjusted for inflation,[23] costs associated with updating the patient consent forms in 2019 would be $0.12 per patient (2018 dollars). SAMHSA used the average number of substance abuse treatment admissions from SAMHSA's 2014–2016 TEDS (1,658,732) as an estimate of the number of clients treated on an annual basis by part 2 programs. Therefore, the total cost burden associated with updating the consent forms to reflect the updated 42 CFR part 2 regulations is estimated to be a one-time cost of $199,048 (1,658,732 * $0.12), as reflected in Table 2, below. Further, the finalized proposal to amend § 2.31 is likely to result in a decrease in the number of consents to disclosures that patients must make, due to the ability to consent to entities without naming a specific individual. Because of a lack of data regarding the number of consents patients have made to multiple individuals within the same entity which would become duplicative as a result of the finalized amendment, we are unable to quantify the reduction in burden related to the expected reduction in the number of required consents.

In prior proposed rules (*e.g.,* 81 FR 7009), SAMHSA estimated one hour of training per staff to achieve proficiency in the 42 CFR part 2 regulations. SAMHSA assumes that training associated with the new requirements discussed in this final rule can be accomplished within the existing one hour of training; therefore, we are not finalizing any additional costs for training counseling staff.

With regard to training materials, SAMHSA will assume responsibility for updating and distributing training materials in year 1 at no cost to part 2 programs. A 2017 study by the Association for Talent Development determined the average time to develop training materials for one hour of classroom instruction is 38 hours.[24] Because we assume that SAMHSA will be updating rather than developing training materials, we estimate the time for training development to be one-half that of developing new materials, or 19 hours and would be performed by an instructor with experience in healthcare at the average wage rate of $63.34 per hour for a health specialty teacher [25] and multiplied the average wage rate by 2 in order to account for benefits and overhead costs. Based on these assumptions, the updating of training materials is estimated to cost $2,407 (19 hours × $126.68/hour). SAMHSA estimates that the updates to consent forms (§§ 2.31 and 2.36) will be one-time costs the first year the final rule will be in effect and will not carry forward into future years. Staff training costs other than those associated with updating training materials are assumed to be ongoing annual costs to part 2 programs, also beginning in the first year that the final rule is in effect. Costs associated with disclosing information to PDMPs (§ 2.36) and agencies (§ 2.53) are assumed to be ongoing annual costs to part 2 programs.

Public Comments

A few commenters expressed their belief that SAMHSA has underestimated the associated training time required for staff to achieve proficiency with the proposed policies. However, these commenters did not suggest a specific alternative estimate.

SAMHSA Response

We believe that the finalized policies do not substantively add requirements for counseling staff, but are instead modifications, revisions, and clarifications to existing requirements. Therefore, we believe the previously approved estimate of one hour is still appropriate and are not making any updates as a result of the comments received.

In section III.L. of this final rule, SAMHSA is finalizing amendments to § 2.67 to extend the period for court-ordered placement of an undercover agent or informant to 12 months, while authorizing courts to further extend a period of placement through a new court order. In that section, SAMHSA is also finalizing changes to explicitly state when the 12- month period begins to run. See section III.L. for further information about this finalized proposal. Since the requirements for seeking this court order will be the same, and the finalized proposal will merely be extending the time of the court order, SAMHSA does not believe this finalized proposal results in any additional regulatory burden.

Based on the above, SAMHSA estimates in the first year that the final rule will be in effect, the costs associated with the finalized updates to 42 CFR part 2 will be $11,425,625 as shown in Table 2. In years 2 through 10, SAMHSA estimates that costs will be $10,372,672. Over the 10-year period of 2020–2029, the total undiscounted cost of the finalized changes will be $104,779,677 in 2018 dollars. As shown in Table 3, when future costs are discounted at 3 percent or 7 percent per year, the total costs become approximately $89.5 million or $73.8 million, respectively. These costs are presented in the tables below.

[22] Williams, A.R., Herman, D.C., Moriarty, J.P., Beebe, T.J., Bruggeman, S.K., Klavetter, E.W. & Bartz, J.K. (2008). HIPAA costs and patient perceptions of privacy safeguards at Mayo Clinic. Joint Commission Journal on Quality and Patient Safety, 34(1), 27–35.

[23] *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-201905.pdf.*

[24] *https://www.td.org/insights/how-long-does-it-take-to-develop-one-hour-of-training-updated-for-2017.*

[25] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, May 2019, Health Specialty Teachers, Postsecondary, Standard Occupations Classification code (25–1071) [*www.bls.gov/oes/current/oes_nat.htm*].

TABLE 2—TOTAL COST OF 42 CFR PART 2 REVISIONS

Year	Disclosure to PDMPs	Staff training costs	Updates to consent forms	Disclosures to agencies	Total costs
2020	$4,257,491	$2,407	$199,048	$6,966,680	$11,425,625
2021	3,405,992	0	0	6,966,680	10,372,672
2022	3,405,992	0	0	6,966,680	10,372,672
2023	3,405,992	0	0	6,966,680	10,372,672
2024	3,405,992	0	0	6,966,680	10,372,672
2025	3,405,992	0	0	6,966,680	10,372,672
2026	3,405,992	0	0	6,966,680	10,372,672
2027	3,405,992	0	0	6,966,680	10,372,672
2028	3,405,992	0	0	6,966,680	10,372,672
2029	3,405,992	0	0	6,966,680	10,372,672
Total	34,911,423	2,407	199,048	69,666,800	104,779,677

TABLE 3—TOTAL COST OF 42 CFR PART 2 REVISIONS—ANNUAL DISCOUNTING

Year	Total costs	Total cost with 3% discounting	Total cost with 7% discounting
2020	$11,425,625	$11,092,840	$10,678,154
2021	10,372,672	9,777,239	9,059,894
2022	10,372,672	9,492,465	8,467,190
2023	10,372,672	9,215,985	7,913,262
2024	10,372,672	8,947,558	7,395,572
2025	10,372,672	8,686,950	6,911,750
2026	10,372,672	8,433,932	6,459,579
2027	10,372,672	8,188,283	6,036,990
2028	10,372,672	7,949,790	5,642,047
2029	10,372,672	7,718,242	5,272,941
Total	104,779,677	89,503,284	73,837,379

We estimated the total annual cost of this rule to be $10,372,672, ignoring initial transition costs (such as training in the first year). In the Paperwork Reduction Act section, we also estimated that the number of clients treated annually by a Part 2 program to be 1,658,732. Thus, the cost and benefits would break even if the average benefit were $6.25 per year per client (even if the benefit accrued to providers or others, rather than directly the client). Based on public comments received from affected providers, organizations and entities that this rule will be burden reducing, a deregulatory description seems reasonable. In addition, we note that the estimated costs of this rule come after the first year from disclosure to PDMPs and new disclosures to agencies. However, this rule removes regulatory barriers to those disclosures. It does not require those disclosures.

Because disclosure to PDMPs is permitted, but not required, by this rule, we assume that such disclosures will only be made when providers (and/or states) have decided that the benefits of that disclosure outweigh the costs. Similarly, this final rule permits new disclosures to agencies, including for audit or research purposes, but does not itself require them. As described above, the rule contains other deregulatory provisions that we have not quantified, such as treatment records from non-Part 2 providers not being covered by Part 2, clarifying sanitation procedures, reducing restrictions on disclosure to organizations with patient consent, and reducing burden/barriers in emergency situations and for research. Thus, this rule is an Executive Order 13771 deregulatory action.

C. Alternatives Considered

In drafting this final rule, SAMHSA considered potential policy alternatives and, when possible, finalized the least burdensome alternatives. For example, in section IV.C. of this final rule, we considered finalizing, specifically, the technological and operational requirements required for segmenting records but decided to allow providers more latitude to define their best practices, understanding that specific requirements could pose more burden, specifically to small and rural providers. In section IV.D. of this final rule, SAMHSA also considered only allowing patients to allow disclosure to state, federal, and local government entities that provide benefits. Instead, however, it decided to finalize to allow patients to more broadly specify disclosure to entities, so that patients can more widely control their information. On balance, SAMHSA believes that the finalized proposals in this rule most appropriately balance the often-competing interests of burden, privacy, and patient safety.

D. Conclusion

SAMHSA finalized amendments to 42 CFR part 2. With respect to our finalized proposals to revise the regulations, SAMHSA does not believe that the finalized proposals will have a significant impact. As discussed above, we are not preparing an analysis for the RFA because SAMHSA has determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities. SAMHSA is not preparing an analysis for section 1102(b) of the RFA because it has determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. In addition, SAMHSA does not believe this final rule imposes substantial direct effects on (1) states,

including subdivisions thereof, (2) the relationship between the federal government and the states, or (3) the distribution of power and responsibilities among the various levels of government. Therefore, the requirements of Executive Order 13132 on federalism would not be applicable.

SAMHSA invited public comments on this section and requests any additional data that would help it to determine more accurately the impact on individuals and entities of the proposed rule. Below are the comments we received as well as our responses.

Public Comments

A few commenters expressed their belief that significant Information Technology barriers involving storing, segmenting, and disclosing/exchanging part 2 information exist which may create disincentives to provide SUD-related services or delays in sharing a patient's SUD record. One commenter recommended that SAMHSA issue a Request for Information to solicit input regarding the specific Health Information Technology (HIT) barriers involved and take steps to address those barriers accordingly. Another commenter stated that while the proposed policies would greatly expand options for our existing service delivery model by allowing clinics to store SUD records in their Electronic Health Record (EHR), the additional capital expense related to purchasing and deploying an upgraded EHR would be prohibitive.

SAMHSA Response

We understand the commenters' concerns and acknowledge that Information Technology challenges and expenses related to the policies being finalized in this rule may exist for certain clinics that provide SUD-related services. However, we believe the specific challenges are not applicable to all SUD providers and are highly unique to those who may experience them to the point where estimating the related expenses would require an assessment of each provider's specific HIT implementation. With specific regard to the cost of upgrading EHR systems, we do not believe the finalized policies would require such an investment and leave the decision to do so to the discretion of each clinic. We thank the commenter for their recommendation that a Request for Information soliciting input on specific HIT barriers be issued, and we will take it under consideration in consultation with ONC.

Public Comments

One commenter expressed its concern regarding additional costs to states to operationalize the segregation of data for PDMPs which may require technological assistance from vendors.

SAMHSA Response

We understand the commenter's concerns and acknowledge that additional costs to states to operationalize the segregation of data for PDMPs may exist for certain states. However, we believe the specific costs may vary substantially and are highly unique to each state to the point where estimating the costs would require an assessment of each state and/or PDMP. We are therefore unable to provide an estimate of the costs states may experience related to this finalized policy.

Public Comments

A few commenters stated their concern that because jurisdictions have not consistently developed or adopted context-specific value sets or machine-readable consent and disclosure rules to allow for automated sensitivity tagging, the updated DS4P standards will result in increased documentation burden and difficult workflows due to the requirement to have to manually tag data as sensitive.

SAMHSA Response

SAMHSA shares the commenters' concerns regarding documentation burden and workflow, however the revised part 2 rule does not involve any update to DS4P standards, and does not impose any requirement for providers to use compliant EHR systems. The revised part 2 rule also does not require non-part 2 providers to segregate any records received from a part 2 program. For these reasons, there is no increased burden to providers under this rule associated with DS4P standards. Any future update to DS4P standards, and any hypothetical burden therefrom, is outside the scope of the current rulemaking. If this issue is addressed through future rulemaking, we may revisit these concerns at that time.

In accordance with the provisions of Executive Order 12866, this final rule has been reviewed by the Office of Management and Budget. 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).

List of Subjects in 42 CFR Part 2

Alcohol abuse, Alcoholism, Drug abuse, Grant programs—health, Health records, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR part 2 as follows:

PART 2—CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 42 U.S.C. 290dd–2.

■ 2. Amend § 2.11 by revising the definition of ''Records'' to read as follows:

§ 2.11 Definitions.

* * * * *

Records means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (*e.g.,* diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts), provided, however, that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient does not become a record subject to this Part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider. Records otherwise transmitted by a part 2 program to a non-part 2 provider retain their characteristic as records in the hands of the non-part 2 provider, but may be segregated by that provider. For the purpose of the regulations in this part, records include both paper and electronic records.

* * * * *

■ 3. Amend § 2.12 by—
■ a. Revising paragraphs (a)(1) introductory text and (a)(1)(ii);
■ b. In paragraph (d)(2)(i)(A) by removing the reference ''§ 2.31(a)(4)(iii)(A)'' and adding in its place the reference ''§ 2.31(a)(4)(i)'';
■ c. Adding paragraph (d)(2)(ii); and
■ d. Revising paragraph (e)(3) and paragraph (e)(4) introductory text.

The revisions and additions read as follows:

§ 2.12 Applicability.

(a) * * *

(1) *Restrictions on disclosure.* The restrictions on disclosure in the regulations in this part apply to any records which:

* * * * *

(ii) Contain drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972

(part 2 program), or contain alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment.

* * * * *

(d) * * *

(2) * * *

(ii) Notwithstanding paragraph (d)(2)(i)(C) of this section, a non-part 2 treating provider may record information about a substance use disorder (SUD) and its treatment that identifies a patient. This is permitted and does not constitute a record that has been re-disclosed under part 2, provided that any SUD records received from a part 2 program or other lawful holder are segregated or segmented. The act of recording information about a SUD and its treatment does not by itself render a medical record which is created by a non-part 2 treating provider subject to the restrictions of this part 2.

* * * * *

(e) * * *

(3) Information to which restrictions are applicable. Whether a restriction applies to the use or disclosure of a record affects the type of records which may be disclosed. The restrictions on disclosure apply to any part 2-covered records which would identify a specified patient as having or having had a substance use disorder. The restriction on use of part 2 records to bring criminal charges against a patient for a crime applies to any records obtained by the part 2 program for the purpose of diagnosis, treatment, or referral for treatment of patients with substance use disorders. (Restrictions on use and disclosure apply to recipients of part 2 records under paragraph (d) of this section.)

(4) *How type of diagnosis affects coverage.* These regulations cover any record reflecting a diagnosis identifying a patient as having or having had a substance use disorder which is initially prepared by a part 2 provider in connection with the treatment or referral for treatment of a patient with a substance use disorder. A diagnosis prepared by a part 2 provider for the purpose of treatment or referral for treatment, but which is not so used, is covered by the regulations in this part. The following are not covered by the regulations in this part:

* * * * *

■ 4. Amend § 2.13 by revising paragraphs (d) introductory text, (d)(2) introductory text, and (d)(3) to read as follows:

§ 2.13 Confidentiality restrictions and safeguards

* * * * *

(d) *List of disclosures.* Upon request, patients who have consented to disclose their patient identifying information using a general designation pursuant to § 2.31(a)(4)(ii)(B) must be provided a list of entities to which their information has been disclosed pursuant to the general designation.

* * * * *

(2) Under this paragraph (d), the entity named on the consent form that discloses information pursuant to a patient's general designation (the entity that serves as an intermediary, as described in § 2.31(a)(4)(ii)(B)) must:

* * * * *

(3) The part 2 program is not responsible for compliance with this paragraph (d); the entity that serves as an intermediary, as described in § 2.31(a)(4)(ii)(B), is responsible for compliance with the requirement.

■ 5. Amend § 2.31 by revising paragraph (a)(4) to read as follows:

§ 2.31 Consent requirements.

(a) * * *

(4)(i) *General requirement for designating recipients.* The name(s) of the individual(s) or the name(s) of the entity(-ies) to which a disclosure is to be made.

(ii) *Special instructions for entities that facilitate the exchange of health information and research institutions.* Notwithstanding paragraph (a)(4)(i) of this section, if the recipient entity facilitates the exchange of health information or is a research institution, a written consent must include the name(s) of the entity(-ies) and

(A) The name(s) of individual or entity participant(s); or

(B) A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed. When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation (see § 2.13(d)).

* * * * *

■ 6. Amend § 2.32 by revising paragraph (a)(1) to read as follows:

§ 2.32 Prohibition on re-disclosure.

(a) * * *

(1) This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65; or

* * * * *

■ 7. Amend § 2.33 by revising paragraph (b) to read as follows:

§ 2.33 Disclosures permitted with written consent.

* * * * *

(b) If a patient consents to a disclosure of their records under § 2.31 for payment or health care operations activities, a lawful holder who receives such records under the terms of the written consent may further disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out payment and/or health care operations on behalf of such lawful holder. In accordance with § 2.13(a), disclosures under this section must be limited to that information which is necessary to carry out the stated purpose of the disclosure. Examples of permissible payment or health care operations activities under this section include:

(1) Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing, and/or related health care data processing;

(2) Clinical professional support services (*e.g.,* quality assessment and improvement initiatives; utilization review and management services);

(3) Patient safety activities;

(4) Activities pertaining to:

(i) The training of student trainees and health care professionals;

(ii) The assessment of practitioner competencies;

(iii) The assessment of provider or health plan performance; and/or

(iv) Training of non-health care professionals;

(5) Accreditation, certification, licensing, or credentialing activities;

(6) Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and/or ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;

(7) Third-party liability coverage;

(8) Activities related to addressing fraud, waste and/or abuse;

(9) Conducting or arranging for medical review, legal services, and/or auditing functions;

(10) Business planning and development, such as conducting cost management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies;

(11) Business management and general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations;

(12) Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;

(13) Resolution of internal grievances;

(14) The sale, transfer, merger, consolidation, or dissolution of an organization;

(15) Determinations of eligibility or coverage (*e.g.,* coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(16) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(17) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(18) Care coordination and/or case management services in support of payment or health care operations; and/or

(19) Other payment/health care operations activities not expressly prohibited in this provision.

* * * * *

■ 8. Amend § 2.34 by—

■ a. Revising paragraph (b);

■ b. Redesignating paragraph (d) as paragraph (e); and

■ c. Adding a new paragraph (d).

The revision and addition read as follows:

§ 2.34 Disclosures to prevent multiple enrollments.

* * * * *

(b) *Use of information limited to prevention of multiple enrollments.* A central registry and any withdrawal management or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not re-disclose or use patient identifying information for any purpose other than the prevention of multiple enrollments or to ensure appropriate coordinated care with a treating provider that is not a part 2 program unless authorized by a court order under subpart E of this part.

* * * * *

(d) *Permitted disclosure by a central registry to a non-member treating provider, to prevent a multiple enrollment.* When, for the purpose of preventing multiple program enrollments or duplicative prescriptions, or to inform prescriber decision making regarding prescribing of opioid medication(s) or other prescribed substances, a provider with a treating provider relationship that is not a member program asks a central registry if an identified patient is enrolled in a member program, the registry may disclose:

(1) The name, address, and telephone number of the member program(s) in which the patient is enrolled;

(2) Type and dosage of any medication for substance use disorder being administered or prescribed to the patient by the member program(s); and

(3) Relevant dates of any such administration or prescription. The central registry and non-member program treating prescriber may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollments or improper prescribing.

* * * * *

■ 9. Add § 2.36 to subpart C to read as follows:

§ 2.36 Disclosures to prescription drug monitoring programs.

A part 2 program or other lawful holder is permitted to report any SUD medication prescribed or dispensed by the part 2 program to the applicable state prescription drug monitoring program if required by applicable state law. A part 2 program or other lawful holder must obtain patient consent to a disclosure of records to a prescription drug monitoring program under § 2.31 prior to reporting of such information.

■ 10. Amend § 2.51 by revising paragraph (a) to read as follows:

§ 2.51 Medical emergencies.

(a) *General rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel to the extent necessary to:

(1) Meet a bona fide medical emergency in which the patient's prior written consent cannot be obtained; or

(2) Meet a bona fide medical emergency in which a part 2 program is closed and unable to provide services or obtain the prior written consent of the patient, during a temporary state of emergency declared by a state or federal authority as the result of a natural or major disaster, until such time that the part 2 program resumes operations.

* * * * *

■ 11. Amend § 2.52 by revising paragraph (a) to read as follows:

§ 2.52 Research.

(a) Notwithstanding other provisions of this part, including paragraph (b)(2) of this section, patient identifying information may be disclosed for the purposes of the recipient conducting scientific research if:

(1) The individual designated as director or managing director, or individual otherwise vested with authority to act as chief executive officer or their designee, of a part 2 program or other lawful holder of part 2 data, makes a determination that the recipient of the patient identifying information is:

(i) A HIPAA-covered entity or business associate that has obtained and documented authorization from the patient, or a waiver or alteration of authorization, consistent with the HIPAA Privacy Rule at 45 CFR 164.508 or 164.512(i), as applicable;

(ii) Subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46), and provides documentation either that the researcher is in compliance with the requirements of 45 CFR part 46, including the requirements related to informed consent or a waiver of consent (45 CFR 46.111 and 46.116) or that the research qualifies for exemption under the HHS regulations (45 CFR 46.104) or any successor regulations;

(iii) Subject to the FDA regulations regarding the protection of human subjects (21 CFR parts 50 and 56) and provides documentation that the research is in compliance with the requirements of the FDA regulations, including the requirements related to informed consent or an exception to, or waiver of, consent (21 CFR part 50) and any successor regulations; or

(iv) Any combination of a HIPAA covered entity or business associate,

and/or subject to the HHS regulations regarding the protection of human subjects, and/or subject to the FDA regulations regarding the protection of human subjects; and has met the requirements of paragraph (a)(1)(i), (ii) (iii), and/or (iv) of this section, as applicable.

(2) The part 2 program or other lawful holder of part 2 data is a HIPAA covered entity or business associate, and the disclosure is made in accordance with the HIPAA Privacy Rule requirements at 45 CFR 164.512(i).

(3) If neither paragraph (a)(1) or (2) of this section apply to the receiving or disclosing party, this section does not apply.

* * * * *

■ 12. Amend § 2.53:

■ a. In paragraph (a) introductory text by removing the reference to ''paragraph (d)'' and adding in its place ''paragraph (f)'';

■ b. By revising paragraph (a)(1)(ii);

■ c. By adding paragraphs (a)(1)(iii);

■ d. In paragraph (b)(1)(iii) by removing the reference to ''paragraph (d)'' and adding in its place ''paragraph (f)'';

■ e. By revising paragraph (b)(2)(ii);

■ f. By adding paragraph (b)(2)(iii)

■ g. By redesignating paragraphs (c) and (d) as paragraphs (e) and (f), respectively;

■ h. By adding new paragraphs (c) and (d);

■ i. In newly redesignated paragraph (e)(1) introductory text, by removing the reference ''paragraph (c)'' and adding in its place the reference ''paragraph (e)'';

■ j. In newly redesignated paragraph (e)(1)(iii), by removing the reference ''paragraph (d)'' and adding in its place the reference ''paragraph (f)'';

■ k. In newly redesignated paragraph (e)(3)(ii)(F), by removing the reference ''paragraph (c)(1)'' and adding in its place the reference ''paragraph (e)(1)'';

■ l. In newly redesignated paragraphs (e)(4) and (5), by removing the reference ''paragraph (c)(2)'' and adding in its place the reference ''paragraph (e)(2)'';

■ m. In newly redesignated paragraph (e)(6), by removing the reference ''paragraph (c)'' and adding in its place the reference ''paragraph (e)'';

■ n. In newly designated paragraph (f), by removing the reference ''paragraph (c)'' and adding in its place ''paragraph (e)'';

■ o. Adding paragraph (g).

The revisions and additions read as follows:

§ 2.53 Audit and evaluation.

(a) * * *

(1) * * *

(ii) Any individual or entity which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a QIO review, or the contractors, subcontractors, or legal representatives of such individual, entity, or quality improvement organization.

(iii) An entity with direct administrative control over the part 2 program or lawful holder.

(b) * * *

(1) * * *

(2) * * *

(ii) Any individual or entity which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a QIO review, or the contractors, subcontractors, or legal representatives of such individual, entity, or quality improvement organization.

(iii) An entity with direct administrative control over the part 2 program or lawful holder.

(c) *Activities included.* Audits and evaluations under this section may include, but are not limited to:

(1) Activities undertaken by a federal, state, or local governmental agency, or a third-party payer entity, in order to:

(i) Identify actions the agency or third-party payer entity can make, such as changes to its policies or procedures, to improve care and outcomes for patients with SUDs who are treated by part 2 programs;

(ii) Ensure that resources are managed effectively to care for patients; or

(iii) Determine the need for adjustments to payment policies to enhance care or coverage for patients with SUD.

(2) Reviews of appropriateness of medical care, medical necessity, and utilization of services.

(d) *Quality assurance entities included.* Entities conducting audits or evaluations in accordance with paragraphs (a) and (b) of this section may include accreditation or similar types of organizations focused on quality assurance.

* * * * *

(g) *Audits and evaluations mandated by statute or regulation.* Patient identifying information may be disclosed to federal, state, or local government agencies, and the contractors, subcontractors, and legal representatives of such agencies, in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using deidentified information.

■ 13. Amend § 2.67 by revising paragraph (d)(2) to read as follows:

§ 2.67 Orders authorizing the use of undercover agents and informants to investigate employees or agents of a part 2 program in connection with a criminal matter.

* * * * *

(d) * * *

(2) Limit the total period of the placement to twelve months, starting on the date that the undercover agent or informant is placed on site within the program. The placement of an undercover agent or informant must end after 12 months, unless a new court order is issued to extend the period of placement;

* * * * *

Dated: June 22, 2020.

Elinore F. McCance-Katz,

Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration.

Approved: July 1, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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Part III

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Deduction for Foreign-Derived Intangible Income and Global Intangible Low-Taxed Income; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9901]

RIN 1545–BO55

Deduction for Foreign-Derived Intangible Income and Global Intangible Low-Taxed Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance regarding the deduction for foreign-derived intangible income (FDII) and global intangible low-taxed income (GILTI). This document also contains final regulations coordinating the deduction for FDII and GILTI with other provisions in the Internal Revenue Code. These regulations generally affect domestic corporations and individuals who elect to be subject to tax at corporate rates for purposes of inclusions under subpart F and GILTI.

DATES:

Effective Date: These regulations are effective on September 14, 2020.

Applicability Dates: For dates of applicability, see §§ 1.250–1(b), 1.962–1(d), 1.1502–50(g), 1.6038–2(m)(4), 1.6038–3(l), and 1.6038A–2(g).

FOR FURTHER INFORMATION CONTACT: Concerning §§ 1.250–1 through 1.250(b)–6, 1.6038–2, 1.6038–3, and 1.6038A–2, Brad McCormack at (202) 317–6911 and Lorraine Rodriguez at (202) 317–6726; concerning § 1.962–1, Edward Tracy at (202) 317–6934; concerning §§ 1.1502–12, 1.1502–13 and 1.1502–50, Michelle A. Monroy at (202) 317–5363 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Background

Section 250 was added to the Internal Revenue Code (''Code'') by the Tax Cuts and Jobs Act, Public Law 115–97, 131 Stat. 2054, 2208 (2017) (the ''Act''), which was enacted on December 22, 2017. On March 6, 2019, the Department of the Treasury (''Treasury Department'') and the IRS published proposed regulations (REG–104464–18) under sections 250, 962, 1502, 6038, and 6038A in the **Federal Register** (84 FR 8188) (the ''proposed regulations''). Corrections to the proposed regulations were published on April 11, 2019, and April 12, 2019, in the **Federal Register** (84 FR 14634 and 84 FR 14901, respectively). A public hearing on the proposed regulations was held on July 10, 2019. The Treasury Department and the IRS also received written comments with respect to the proposed regulations.

All written comments received in response to the proposed regulations are available at *https://www.regulations.gov* or upon request. Terms used but not defined in this preamble have the meaning provided in these final regulations.

Summary of Comments and Explanation of Revisions

I. Overview

The final regulations retain the basic approach and structure of the proposed regulations, with certain revisions. This Summary of Comments and Explanation of Revisions section discusses those revisions as well as comments received in response to the solicitation of comments in the notice of proposed rulemaking. Comments outside the scope of this rulemaking are generally not addressed but may be considered in connection with future guidance projects.

II. Comments on and Revisions to Documentation Requirements and Applicability Dates

A. Documentation Requirements for Foreign Persons, Foreign Use, and Location Outside the United States

As described in parts VII.B, C.1, and D.1 and VIII.B.1 and B.2.c of this Summary of Comments and Explanation of Revisions section, the proposed regulations provided that to establish that a recipient is a foreign person, property is for a foreign use (within the meaning of proposed § 1.250(b)–4(d) and (e)), or a recipient of a general service is located outside the United States (within the meaning of proposed § 1.250(b)–5(d)(2)), the taxpayer must obtain specific types of documentation described in proposed §§ 1.250(b)–4(c)(2), (d)(3), and (e)(3) and 1.250(b)–5(d)(3) and (e)(3). The proposed regulations also provided a transition rule whereby for taxable years beginning on or before March 4, 2019, taxpayers could use any reasonable documentation maintained in the ordinary course of the taxpayer's business that establishes that a recipient is a foreign person, property is for a foreign use, or a recipient of a general service is located outside the United States, as applicable, in lieu of the specific documentation described in the regulations, provided that such documentation meets certain reliability requirements described in proposed § 1.250(b)–3(d). See proposed § 1.250–1(b). The preamble requested comments on this special transition rule.

Several comments recommended either making this transition rule permanent or extending it for a certain period after the regulations are finalized. The comments recommending that the transition rule be made permanent indicated that the documentation described in the proposed regulations may be difficult, if not impossible, to obtain in the ordinary course of business. The comments noted that customers are highly reluctant to provide some of the types of documents that the proposed regulations described. A comment noted that the documentation rules in the proposed regulations could require taxpayers to renegotiate contracts or make inquiries of their customers that could interfere with the customer relationship. Several comments were concerned with how the documentation rules and, in particular, the reliability requirements would apply to business models with longer-term contracts, especially those entered into during the 2019 tax year.

The comments that requested extending the transition rule suggested that this would allow adequate time for the IRS to gain experience with the types of documentation taxpayers collect in the ordinary course of business, and for taxpayers to gain experience complying with such rules by developing or improving internal compliance systems. Alternatively, some comments suggested that the next issuance of regulations should be in temporary form to allow additional time to consider the reasonableness of the documentation requirements before final regulations are issued and to allow taxpayers more time to identify distortive results.

Other comments recommended changes to the documentation rules if the final regulations do not make the transition rule permanent. Several comments suggested that any list of suitable documents (for either property sales or services) should be non-exclusive and include more documents obtained in the ordinary course of business. Some comments recommended allowing the use of documentation methods similar to those for sales of fungible mass property under proposed § 1.250(b)–4(d)(3)(iii) such as market research, statistical sampling, economic modeling or other similar methods to show foreign person status or foreign use.

The final regulations address these comments in several ways. First, the final regulations eliminate the requirement in the proposed regulations to obtain specific types of documents to

establish foreign person status, foreign use with respect to sales of certain general property that are made directly to end users, and the location of general services provided to consumers. The Treasury Department and the IRS have determined that requiring specific documentation with respect to these requirements is difficult given the variations in industry practices and is not necessary to achieve the purpose of the statute. Accordingly, the final regulations remove the specific documentation requirements to establish foreign person status and foreign use with respect to certain sales of general property and the location of a consumer of a general service. However, as explained in more detail in part II.D of this Summary of Comments and Explanation of Revisions section, as with any deduction, taxpayers claiming a deduction under section 250 bear the burden of demonstrating that they are entitled to the deduction. Therefore, the general requirement for taxpayers to substantiate their deductions will apply without any additional specific requirements as to the content of information or documents.

Second, the final regulations adopt a more flexible approach regarding the types of substantiation required for foreign use with respect to sales of general property to non-end users, foreign use with respect to sales of intangible property, and with respect to determining whether services are performed for business recipients located outside the United States. Although the substantiation requirements in the final regulations are more specific as to the nature of the information required, they are not limited to a narrow set of documents. The requirements also do not contain the specific reliability requirement set out in the proposed regulations because the reliability of documents or information can differ depending on the circumstances. For example, documents created in advance of a sales date (such as a long-term sales contract) may be as reliable as documents created at the time of the sale, depending on the facts and circumstances. Further, the final regulations continue to require that the substantiating documents be supported by credible evidence. See part II.C of this Summary of Comments and Explanation of Revisions section.

Finally, the applicability dates of the regulations have been revised, and taxpayers are permitted to rely on the proposed regulations for taxable years before the final regulations are applicable, including relying on the transition rules during the entirety of such period. See part II.F and XII of this Summary of Comments and Explanation of Revisions section.

B. Specific Substantiation for Certain Transactions

In lieu of the documentation requirements in the proposed regulations, with respect to sales of general property to recipients other than end users, sales of intangible property, and general services provided to business recipients, the final regulations provide substantiation rules that are more flexible with respect to the types of corroborating evidence that may be used. See § 1.250(b)–3(f). For these transactions, specific substantiation requirements are needed to ensure that taxpayers make sufficient efforts to determine whether the regulatory requirement is met. Therefore, with respect to these transactions, the final regulations describe the type of information necessary to meet the substantiation requirements. The specific ways a taxpayer must substantiate these elements are described in parts VII.C.9, VII.D.2, and VIII.B.2.d of this Summary of Comments and Explanation of Revisions section. The substantiation requirements are modeled after substantiation rules under section 170 (requiring substantiation through receipts for certain charitable deductions) and section 274(d) (requiring substantiation by adequate records or a taxpayer statement with corroborating evidence). The Treasury Department and the IRS have determined that requiring a taxpayer to specifically substantiate certain transactions—in particular transactions where the relevant facts needed to satisfy the rules are generally in the hands of a third party with a business relationship with the taxpayer—is necessary and appropriate for establishing ''to the satisfaction of the Secretary'' that property is sold for a foreign use or that services are provided to persons located outside the United States. See section 250(b)(4) and (b)(5)(C).

C. Timing To Obtain, Maintain, and Provide Specific Substantiation

In general, the substantiation rules require that the substantiating documents with respect to certain transactions that give rise to foreign-derived deduction eligible income (a ''FDDEI transaction'') be in existence by the time the taxpayer files its return (including extensions) with respect to the FDDEI transaction (the ''FDII filing date''). See § 1.250(b)–3(f)(1). The final regulations do not impose additional requirements relating to when substantiating documents must be in existence. However, the timing of when substantiating documents are created may affect the credibility of the substantiating documents. For example, substantiating documents created at or near the time of the transaction generally have a higher degree of credibility as compared to substantiating documents created later in time. With respect to long-term contracts, substantiating documents created when the transaction was entered into will be more credible in later years if the taxpayer periodically confirms that the terms of the long-term contract are being adhered to.

The final regulations provide that substantiating documents must be provided to the IRS upon request, generally within 30 days or some other period agreed upon by the IRS and the taxpayer. See § 1.250(b)–3(f)(1). This is necessary to allow the substantiation requirements to serve their purpose, including to allow the IRS to timely examine the taxpayer's qualification for the FDII deduction.

D. Substantiation in All Other Cases

For the rules in the final regulations for which there are no specific substantiation requirements, taxpayers are already required under section 6001 to make returns, render statements, and keep the necessary records to show whether such person is liable for tax under the Code. Therefore, a taxpayer claiming a deduction under section 250 will still be required to substantiate that it is entitled to the deduction even if it is not subject to the specific substantiation requirements contained in the final regulations. See § 1.6001–1(a); *INDOPCO* v. *Commissioner,* 503 U.S. 79, 84 (1992) (''an income tax deduction is a matter of legislative grace and . . . the burden of clearly showing the right to the claimed deduction is on the taxpayer'' (internal citations omitted)).

The Treasury Department and the IRS expect that taxpayers may use a broader range of evidence to substantiate a section 250 deduction under the new substantiation requirements (and section 6001 where no specific substantiation requirements are provided) than they would have been able to use under the more specific documentation requirements detailed in the proposed regulations. Based on comments received, in many cases a taxpayer will be able to determine whether it meets the requirements in the final regulations using documents maintained in the ordinary course of its business, as provided in the transition rule. In some circumstances, however, it may be necessary for taxpayers to gather

additional information to establish that a requirement is met. The Treasury Department and the IRS are also considering issuing additional administrative guidance on acceptable documentation to substantiate the deduction.

E. Small Business Exception

The final regulations include an exception for small businesses similar to the exceptions from the documentation requirements for small businesses that are in the proposed regulations. See proposed §§ 1.250(b)–4(c)(2)(ii)(A) and (d)(3)(ii)(A), and 1.250(b)–5(d)(3)(ii)(A) and (e)(3)(ii)(A). The exception provides that the substantiation requirements described generally in part II.B of this Summary of Comments and Explanation of Revisions section do not apply if the taxpayer and all related parties of the taxpayer, in the aggregate, receive less than $25,000,000 in gross receipts during the prior taxable year. See § 1.250(b)–3(f)(2). In response to comments that the final regulations should allow for broader application of the small business exception, the final regulations modify the threshold amount to qualify for that exception from $10,000,000 of gross receipts received by the seller of general property or renderer of services in the prior taxable year (the standard used in the proposed regulations) to $25,000,000 in gross receipts received by the taxpayer and all related parties. As a result of this exception, a small business will not need to satisfy the specific substantiation requirements in the regulations, although it must continue to comply with the general substantiation rules under section 6001. For example, small businesses may be able to substantiate that a sale of general property is for a foreign use by having evidence of a foreign shipping address and memorializing conversations with the recipients explaining where the property will be resold, if sufficiently reliable, or having a copy of an export bill of lading.

F. Transition Rules

The final regulations modify the applicability dates of the regulations to give taxpayers additional time to develop systems for complying with the regulations. Generally, the final regulations are applicable for taxable years beginning on or after January 1, 2021. See § 1.250–1(b). This applicability date ensures that all taxpayers, regardless of whether they are fiscal- or calendar-year taxpayers, have at least three full taxable years after the Act was enacted before the final regulations become applicable. However, for taxable years beginning before January 1, 2021, taxpayers may apply the final regulations or rely on the proposed regulations, except that taxpayers that choose to rely on the proposed regulations may rely on the transition rule for documentation for all taxable years beginning before January 1, 2021 (rather than only for taxable years beginning on or before March 4, 2019, which was the limitation contained in the proposed regulations).

III. Comments on and Revisions to Proposed § 1.250(a)–1—Deduction for Foreign-Derived Intangible Income and Global Intangible Low-Taxed Income

Proposed § 1.250(a)–1 provided general rules to determine the amount of a taxpayer's section 250 deduction and associated definitions that apply for purposes of the proposed regulations.

A. Pre-Act NOLs

Several Code sections, including section 250, include limitations based on a taxpayer's taxable income or a percentage of taxable income. The proposed regulations provided an ordering rule for applying sections 163(j) and 172 in conjunction with section 250 that provided that a taxpayer's taxable income for purposes of applying the taxable income limitation of section 250(a)(2) is determined after all of the corporation's other deductions are taken into account, without distinguishing between pre-Act and post-Act net operating losses (''NOLs''). See proposed § 1.250(a)–1(c)(4).

Several comments noted that the proposed regulations did not explicitly address the impact of pre-Act NOLs on the deduction under section 250 and recommended that pre-Act NOLs not be taken into account for purposes of determining the deduction limit under section 250(a)(2). This would allow taxpayers to take a deduction under section 250 for FDII in lieu of utilizing available pre-Act NOLs.

Section 250(a)(2) limits the FDII deduction based on ''taxable income,'' which is defined in section 63 to include gross income minus deductions, including NOL deductions under section 172. Section 250(a)(2) contains no language that would support ignoring pre-Act NOLs for purposes of determining the amount of taxable income for purposes of section 250(a)(2). Cf. section 965(n) (providing an election to forgo usage of a portion of pre-Act NOLs against a taxpayer's inclusion under section 965). Therefore, the comment is not adopted.

B. Ordering Rule

As discussed in the previous section, the deduction under section 250 is subject to a taxable income limitation under section 250(a)(2). Proposed § 1.250(a)–1(c)(4) provided that the corporation's taxable income is determined with regard to all items of income, deduction, or loss, except for the deduction allowed under section 250. *Example 2* in proposed § 1.250(a)–1(f)(2) applied the ordering rule with respect to sections 163(j), 172, and 250.

Some comments recommended that the regulations eliminate the ordering rule in favor of an approach that used simultaneous equations to compute taxable income for each Code provision that referred to taxable income, whereas other comments expressed concern with the complexity of performing simultaneous equations. One comment recommended that the regulations not consider section 163(j) and 172(b) carryforwards or carrybacks.

The Treasury Department and the IRS have determined that further study is required to determine the appropriate rule for coordinating section 250(a)(2), 163(j), 172, and other Code provisions (including, for example, sections 170(b)(2), 246(b), 613A(d), and 1503(d)) that limit the availability of deductions based, directly or indirectly, upon a taxpayer's taxable income. Therefore, the final regulations remove *Example 2* in proposed § 1.250(a)–1(f)(2) and reserve a paragraph in § 1.250(a)–1(c)(5)(ii) for coordinating section 250(a)(2) with other provisions calculated based on taxable income. The Treasury Department and the IRS are considering a separate guidance project to address the interaction of sections 163(j), 172, 250(a)(2), and other Code sections that refer to taxable income; this guidance may include an option to use simultaneous equations in lieu of an ordering rule.[1] Comments are requested in this regard.

Before further guidance is issued regarding how allowed deductions are taken into account in determining the taxable income limitation in section 250(a)(2), taxpayers may choose any reasonable method (which could include the ordering rule described in the proposed regulations or the use of simultaneous equations) if the method

[1] Any separate guidance would take into account the recent addition of section 172(a)(2)(B)(ii)(I) by the Coronavirus Aid, Relief, and Economic Security Act, Public Law 116–136, 134 Stat. 281 (2020). That provision provides in relevant part that, for taxable years beginning after December 31, 2020, the taxable income limitation for purposes of deducting net operating loss carrybacks and carryovers is determined without regard to the deductions under sections 172, 199A, and 250.

is applied consistently for all taxable years beginning on or after January 1, 2021.

C. Carryovers of Excess FDII

Consistent with the statute, the proposed regulations did not contain any provision allowing the carryforward or carryback of a tax year's FDII deduction in excess of the taxpayer's taxable income limitation under section 250(b)(2) and proposed § 1.250(a)–1(b)(2). One comment argued that a provision allowing the carryforward or carryback should be added because the taxable income limitation frustrates the policy goal of the FDII regime of reducing the tax incentive to locate intellectual property outside the United States. A different comment recommended that where the taxable income limitation of the proposed regulations applies to a given tax year, the final regulations should allow for the creation of a FDII recapture account by which taxpayers can carry forward previously unused section 250 deductions to future tax years when they have enough taxable income to use these deductions. In contrast, another comment recommended that, consistent with the statute, the final regulations should not allow for carrybacks or carryforwards in order to limit the potential for abuse by taxpayers.

The section 250 deduction is an annual calculation, and nothing in the statute or legislative history contemplates the creation of carryforwards or carrybacks or a recapture account. Cf. section 163(j)(2) (providing for the carryforward of disallowed business interest). As a result, the final regulations do not adopt these recommendations.

D. Definition of GILTI

The final regulations under section 250 revise the definition of GILTI consistent with the final regulations under section 951A (''section 951A final regulations''). The term ''GILTI'' means, with respect to a domestic corporation for a taxable year, the corporation's GILTI inclusion amount under § 1.951A–1(c) for the taxable year. See § 1.250(a)–1(c)(3).

IV. Comments on and Revisions to Proposed § 1.250(b)–1—Computation of Foreign-Derived Intangible Income

The proposed regulations provided that a taxpayer's FDII is the taxpayer's deemed intangible income (''DII'') multiplied by the corporation's foreign-derived ratio. See proposed § 1.250(b)–1(b). A taxpayer's DII is the excess (if any) of the corporation's deduction eligible income (''DEI'') over its deemed tangible income return (''DTIR''). See proposed § 1.250(b)–1(c)(3). A taxpayer's DTIR is 10 percent of the taxpayer's qualified business asset investment (''QBAI''). See proposed § 1.250(b)–1(c)(4). The foreign-derived ratio is the taxpayer's ratio of foreign-derived deduction eligible income (''FDDEI'') to DEI. See proposed § 1.250(b)–1(c)(13).

A. Financial Services Income

Section 250(b)(3)(A)(i)(III) excludes from DEI financial services income as defined in section 904(d)(2)(D). One comment requested a clarification that income that falls outside of the definition of section 904(d)(2)(D) should be eligible for inclusion in DEI, such as leasing or financing activities outside of the active conduct of a banking, financing, or similar business.

Section 250(b)(3)(A)(i)(III) excludes only financial services income as defined in section 904(d)(2)(D). Any leasing or financing activities that are not described in section 904(d)(2)(D) will not fall within this exclusion. Therefore, no changes are necessary.

Another comment suggested that the proposed regulations do not provide enough general guidance on non-active financial services income from financial instruments (such as derivatives and hedges), and, in particular, how to characterize such income (or losses) as a FDDEI transaction. Absent such guidance, the comment asserts that taxpayers could take inconsistent positions in characterizing a derivative or hedge and characterizing the underlying transaction as FDDEI transactions. This comment recommended adding a general rule that associates the income, loss, and expenses of a derivative or hedge with the underlying transaction. Alternatively, the comment suggested that the final regulations treat the derivative or hedge transaction as a separate transaction and test it for FDDEI under the rules regarding sales of intangible property.

Consistent with the proposed regulations, the final regulations provide that, in general, financial instruments are neither general property nor intangible property, and therefore their sales cannot give rise to FDDEI. See § 1.250(b)–3(b)(10) (excluding from the definition of general property a security defined under section 475(c)(2)) and § 1.250(b)–3(b)(11) (intangible property has the meaning set forth in section 367(d)(4)). However, the final regulations adopt the suggestion to provide a special rule for hedges to associate the income or loss from such hedges with the underlying transaction. See § 1.250(b)–4(f) and part VII.E of this Summary of Comments and Explanation of Revisions section.

B. Definition of Foreign Branch Income

Section 250(b)(3) excludes from DEI foreign branch income as defined in section 904(d)(2)(J), which provides that foreign branch income is business profits attributable to one or more qualified business units. Proposed § 1.250(b)–1(c)(11) defined foreign branch income by cross-reference to § 1.904–4(f)(2), which provides that gross income is attributable to a foreign branch if the gross income is reflected on the separate set of books and records of the foreign branch. Proposed § 1.250(b)–1(c)(11), however, modified this definition to also include any income from the sale, directly or indirectly, of any asset (other than stock) that produces gross income attributable to a foreign branch, including by reason of the sale of a disregarded entity or partnership interest.

Several comments requested that the final regulations remove the modification to the definition in proposed § 1.904–4(f)(2). Several comments noted that the definition, as proposed, would impermissibly create a class of income that is neither DEI nor foreign branch income for section 904 foreign tax credit purposes, and therefore, asserted that the definitions must be aligned consistently. Another comment argued that the proposed regulations under section 904 already contain rules that address the types of transactions that were described in proposed § 1.250(b)–1(c)(11). Multiple comments also noted that section 250(b)(3)(A)(i)(VI) cross references to section 904(d)(2)(J) without any modification to that latter provision and argued that modifying the definition in regulations exceeded the Treasury Department and IRS's regulatory authority. One comment argued that the expansion contravenes the Congressional purpose behind FDII of encouraging the repatriation of intangible property. Another comment noted that if the definition with the modification is applied retroactively, it could adversely affect taxpayers that undertook transactions to repatriate intellectual property before the proposed regulations were issued, a problem that the comment asserted is exacerbated by the differing effective dates of the proposed foreign tax credit regulations and the FDII proposed regulations.

If the final regulations were to retain the expanded definition, one comment requested that the definition also be

used for purposes of the foreign branch category definition in § 1.904–4(f). Another comment requested that the final regulations provide further clarification of the treatment of the disregarded transactions, particularly with respect to the disposition of a partnership interest, and provide relevant examples of other types of transactions that the expanded definition is intended to capture. Moreover, the comment requested that the definition of foreign branch income should be modified such that it would not include any adjustments that would increase the gross income attributable to the foreign branch as a result of the transfer of intangible property from the foreign branch to the foreign branch owner.

The Treasury Department and the IRS agree that there should be one consistent definition of foreign branch income in both §§ 1.250(b)–1(c)(11) and 1.904–4(f)(2) to avoid the various results suggested by comments. Accordingly, the final regulations define foreign branch income by cross reference to § 1.904–4(f)(2) and remove the modification to that definition in the proposed regulations that would have included as foreign branch income any income from the sale, directly or indirectly, of any asset (other than stock) that produces gross income attributable to a foreign branch, including by reason of the sale of a disregarded entity or partnership interest. See § 1.250(b)–1(c)(11).[2]

C. Cost of Goods Sold Allocation

The proposed regulations provided that for purposes of determining the gross income included in gross DEI and gross FDDEI, cost of goods sold is attributed to gross receipts with respect to gross DEI or gross FDDEI under any reasonable method. See proposed § 1.250(b)–1(d)(1). The final regulations clarify that the method chosen by the taxpayer must be consistently applied.

For purposes of this rule, any cost of goods sold associated with activities undertaken in an earlier taxable year cannot be segregated into component costs and attributed disproportionately to amounts excluded from gross FDDEI or to amounts excluded from gross DEI, similar to the rules in proposed § 1.199–4(b)(2)(iii)(A). The preamble to the proposed regulations requested comments on whether there are alternative approaches for dealing with timing issues, and whether additional rules should be provided for attributing cost of goods sold in determining gross DEI and gross FDDEI.

One comment recommended that the final regulations continue to allow cost of goods sold to be allocated under any reasonable method to provide flexibility to different taxpayers. Another comment agreed with the proposed regulations that cost of goods sold should be allocated between gross FDDEI and gross non-FDDEI[3] regardless of whether any component of the costs was associated with activities undertaken in a prior tax year. That comment, however, recommended that for future periods taxpayers that recognized revenue under section 451 for advance payments should be permitted an election to create an imputed cost of goods sold deduction based upon the taxpayer's gross profit percentage for that particular product or service. The comment argued this election is needed because recognition of an advance payment as income without associated cost of goods sold might be required under section 451 based upon certain facts and circumstances and the election would allow the taxpayer to avoid this distortive impact.

Sections 451 and 461 provide the general rules on the timing of income recognition and taking a deduction into account, respectively. Nothing in section 250 suggests that Congress intended to change the scope of generally applicable income recognition rules. Therefore, the final regulations do not adopt the comment to permit an election to create an imputed cost of goods sold deduction in the context of advance payments with respect to section 250.

D. Expense Allocation

1. In General

In calculating DEI under section 250(b)(3), a taxpayer must determine the deductions that are ''properly allocable'' to gross DEI. Proposed § 1.250(b)–1(d)(2)(i) further provided that, for purposes of calculating FDDEI, a taxpayer must determine the deductions that are ''properly allocable'' to gross FDDEI. Consistent with the rules for determining the foreign tax credit limitation under section 904 or qualified production activities income under former section 199, the proposed regulations provided that §§ 1.861–8 through 1.861–14T and 1.861–17 apply for purposes of allocating deductions to gross DEI and gross FDDEI. Id. Several comments supported using these general apportionment rules.

2. Research and Experimentation Expenditures

Under § 1.861–17(b), an exclusive apportionment of research and experimentation (''R&E'') expenditures is made if activities representing more than 50 percent of the R&E expenditures were performed in a particular geographic location, such as the United States. After this initial exclusive apportionment, the remainder of the taxpayer's R&E expenditures are apportioned under either the sales or gross income methods under § 1.861–17(c) and (d). Section 1.861–17(e) provides rules for making a binding election to use either the sales or gross income method.

a. Exclusive Apportionment and Direct Apportionment

The proposed regulations under section 250 specified that the exclusive apportionment rules in § 1.861–17(b) did not apply for purposes of apportioning R&E expenses to gross DEI and gross FDDEI. See proposed § 1.250(b)–1(d)(2)(i). Several comments requested that the final regulations allow taxpayers to use exclusive apportionment for purposes of determining FDII. One comment noted that the preamble to the proposed regulations does not justify the proposed regulations omitting the exclusive apportionment method in the FDII context. Another comment asserted that allowing exclusive apportionment would mitigate a significant disincentive for taxpayers to onshore intangible property into the United States. Other comments argued that allocating R&E expenses to FDDEI may discourage taxpayers from performing R&E activities in the United States.

Several comments recommended allocating R&E expenditures based on an optional books and records method that could be used when there is a clear factual relationship between the R&E expenditures and a particular amount of income. These comments noted that some taxpayers are subject to regulatory oversight with respect to their contract pricing and costs, and therefore such taxpayers' books and records could be an accurate way of showing the relationship between R&E expenses and gross income.

Several comments also requested that the final regulations adopt special rules for expenses that are market-restricted or market-required (for example, expenses required only by the U.S. Food

[2] Under § 1.904–4(f)(2), a disposition of an interest in a disregarded entity could still result in foreign branch income. See § 1.904–4(f)(4)(ii) *Example 2.*

[3] The final regulations rename ''gross non-FDDEI'' as ''gross RDEI'' to clarify that the term includes only the residual of gross DEI that is not gross FDDEI, rather than all gross income (including income that is not gross DEI) that is not gross FDDEI. See § 1.250(b)–1(c)(14).

and Drug Administration concerning the U.S. market), including where the legally mandated rule in § 1.861–17(a)(4) would not apply. One comment noted that this rule could apply in situations where U.S. law limits the realization from certain research activities to the market in which the research is performed (such as export controls) and therefore the R&E expenditures would not be expected to generate gross income outside the United States.

Several comments requested that if none of these recommendations for allocating R&E expenses are adopted, the final regulations should reserve on this provision pending the broader ongoing review of § 1.861–17 by the Treasury Department.

In light of the issuance of proposed rules under § 1.861–17 on December 17, 2019 (84 FR 69124) (the ''2019 FTC proposed regulations''), the final regulations remove the provision stating that the exclusive apportionment rules in § 1.861–17(b) do not apply for purposes of apportioning R&E expenses to gross DEI and gross FDDEI, and generally do not provide special rules for applying § 1.861–17 for purposes of section 250. Proposed § 1.861–17 in the 2019 FTC proposed regulations provides that the exclusive apportionment rule applies only to section 904 as the operative section, and also proposes eliminating the special rule for legally mandated R&E. As recommended by comments to the proposed regulations under section 250, the Treasury Department and the IRS will consider the issues raised regarding the application of exclusive apportionment for purposes of section 250 as part of finalizing the 2019 FTC proposed regulations.

b. Use of Sales or Gross Income Method

Several comments requested that the final regulations include an election to allocate R&E expenses under either the sales or gross income method. Comments also requested that taxpayers should be permitted to make this election annually to give taxpayers a longer period to assess the various new regimes that rely on § 1.861–17 such as section 250, and pending the finalization of the FDII regulations. Another comment suggested that the final regulations should provide that the provisions of § 1.861–17(c)(3) (requiring sales to third parties by controlled foreign affiliates to be included) should not apply as it might artificially apportion more R&E expense against FDDEI.

As described in the preamble to proposed § 1.861–17 in the 2019 FTC proposed regulations, the Treasury Department and the IRS are concerned that the gross income method could in some cases produce inappropriate results. See 84 FR 69124, 69129. As a result, the 2019 FTC proposed regulations proposed to eliminate the optional gross income method described in § 1.861–17(d) and require R&E expenditures in excess of the amount exclusively apportioned under § 1.861–17(b) to be apportioned based on gross receipts. See proposed § 1.861–17(d). Comments addressing the applicability of the gross income method will be addressed as part of finalizing the 2019 FTC proposed regulations.

Proposed § 1.861–17(e)(3), published December 7, 2018 (83 FR 63200), permitted taxpayers a one-time exception to what would otherwise be a five-year binding election period under § 1.861–17(e)(1) to use either the sales or the gross income method, in light of the many changes to the foreign tax credit rules made by the Act. Under proposed § 1.861–17(e)(3), even if a taxpayer is subject to the binding election period, for the taxpayer's first taxable year beginning after December 31, 2017, the taxpayer may change its apportionment method without obtaining the Commissioner's consent. Comments to the proposed regulations under section 250 requested that this one-time exception be extended to at least a second tax year beginning after December 31, 2017, potentially at the election of the taxpayer, pending the Treasury Department's ongoing review of § 1.861–17. The final regulations under § 1.861–17 issued on December 17, 2019, provide an additional year for taxpayers to change their election of the sales or gross income method. See § 1.861–17(e)(3).

3. Carryovers

Comments requested additional clarification regarding whether taxpayers are required to apportion expenses incurred before the effective date of the proposed regulations. Multiple comments specifically asked for a clarification that taxpayers are not required to apportion NOLs incurred before the effective date of the proposed regulations or, in some cases, before the effective date of the Act, recommending that a clarification could be along the lines of § 1.199–4(c)(2)(ii) (providing that a deduction under section 172 for a net operating loss is not allocated or apportioned to domestic production gross receipts or gross income attributable to domestic production gross receipts).

The final regulations address this comment by providing that the following provisions (which limit certain deductions and provide for the carryover of the amounts not currently allowed) do not apply when allocating and apportioning deductions to gross DEI or gross FDDEI of a taxpayer for a taxable year: Sections 163(j), 170(b)(2), 172, 246(b), and 250. See § 1.250(b)–1(d)(2)(ii). The Treasury Department and the IRS considered a rule that would require expenses incurred in prior years, including in years before the effective date of the proposed regulations, to be allocated to gross DEI and gross FDDEI, but determined that the benefit of the theoretical precision of this approach would be outweighed by the burden on taxpayers and the IRS that would be associated with making retroactive determinations. Further, the approach taken in the final regulations is consistent with the premise that the section 250 deduction is calculated based on annual income and expenses.

E. Foreign-Derived Ratio

The proposed regulations provided rules for determining a taxpayer's foreign-derived ratio, which is the ratio of FDDEI to DEI. See proposed § 1.250(b)–1(c)(13). The preamble to the proposed regulations observed that as a result of expense apportionment or attribution of cost of goods sold to gross receipts, a taxpayer's FDDEI could exceed its DEI, thereby resulting in a foreign-derived ratio greater than one. The preamble noted that this result would be inconsistent with section 250(b)(4), which defines FDDEI as a subset of DEI, as it would lead to having FDII in excess of DII. Therefore, the proposed regulations clarified that the foreign-derived ratio cannot exceed one.

Several comments requested that the final regulations allow the foreign-derived ratio to exceed one. The comments asserted that the foreign-derived ratio can in fact exceed one under the statute where the taxpayer has losses that cause its FDDEI to exceed its DEI, and that there is no evidence Congress intended to limit the foreign-derived ratio to no greater than one. One of the comments asserted that FDDEI and DEI are defined by the statute and that the Treasury Department and the IRS do not have the authority to define FDDEI more narrowly than the statute does. Another comment argued that section 250(a)(2) provides a separate taxable income limitation that limits the FDII deduction based on domestic losses. This comment further asserted that the foreign-derived ratio rule of the proposed regulations reduces a taxpayer's incentive for repatriating intangible property when the foreign income from these intangibles cannot be

used to offset domestic losses for purposes of applying section 250.

One comment further suggested that the final regulations allow a taxpayer to elect to determine its FDII deduction, including the various elements of the determination such as DII, QBAI, and DTIR, based on specific product lines or business lines, as determined by the taxpayer. The comment asserted that such an approach would be analogous to other provisions that calculate taxable income separately for different subsets of income such as former section 199, the foreign tax credit limitation under section 904(d), separate limitation loss recapture rules in sections 904(f) and (g), and §§ 1.994–1(c) and 1.994–2(b). The comment argued that such an approach to determining FDII is more consistent with the policy goal of reducing the tax incentive to locate intellectual property outside the United States, which the comment asserted would be frustrated if domestic losses reduce FDII-eligible income.

The Treasury Department and the IRS do not agree that limiting the foreign-derived ratio to no greater than one is inconsistent with the plain meaning of section 250. Specifically, the approach recommended by the comments would be inconsistent with the statutory language of section 250(b)(4), which defines FDDEI as a subset of DEI, that is, ''any deduction eligible income of such taxpayer which is derived in connection with'' certain transactions. Allowing the foreign-derived ratio to exceed one could also lead to anomalous results. For example, a cliff effect would arise whereby a taxpayer with significant FDDEI but only $1 of DEI would have a significant FDII deduction, whereas if it has $0 or less of DEI, then no FDII deduction would be allowed. This would also create further anomalous results and incentives with respect to section 163(j), which is determined taking into account the section 250 deduction.

In addition, nothing in section 250 provides for FDII to be calculated based on specific product lines or business lines, which would entail significant complexity for taxpayers and administrative burdens for the IRS. Instead, the statute is clear that the FDII deduction is calculated as an aggregate of all FDDEI transactions. Therefore, the final regulations do not adopt this comment.

F. Partnership Reporting Requirements

The proposed regulations required partnership information reporting in order to administer section 250. See proposed §§ 1.250(b)–1(e)(2) and 1.6038–3(g)(4). One comment asserted that the partnership information reporting requirements of proposed § 1.250(b)–1(e)(2) impose unnecessary administrative burdens on a partnership that reasonably believes it has no (direct or indirect) domestic corporate partners, even after the partnership has performed reasonable due diligence as to the identity of its partners and reasonably relied on information provided by the partners. The comment requested that the Treasury Department and IRS consider some form of relief from this reporting; the comment expressed the view that this limited reporting requirement would not prejudice the government's interest because the use of partnership items can only reduce the partner's tax liability. The comment further requested the addition of a reasonable cause exception (consistent with the penalty defenses available for the Form 8865 penalties).

The final regulations do not include a more limited reporting requirement because the Treasury Department and IRS are concerned that this might undermine accurate reporting at the partner level. In addition, the Treasury Department and IRS disagree with the comment's observation that reporting by the partnership of items under section 250 could only reduce a partner's tax liability—for example, a domestic corporate partner might reduce its tax liability by failing to include partnership QBAI. As to the comment's request for a reasonable cause exception, generally applicable penalty exceptions already apply to the extent information relevant to FDII is not reported on the applicable form. See section 6698(a) for filing Form 1065, section 6038(c)(4)(B) for filing Form 8865, and section 6724(a) for filing Schedule K–1 (Form 1065). For example, under § 301.6724–1(a)(2)(ii) and (c)(6), a partnership may establish reasonable cause because a payee failed to provide information necessary for the partnership to comply (or because of incorrect information provided by the payee or any other person that the partnership relied on in good faith). However, the final regulations clarify the reporting rules for tiered-partnership situations as well as provide guidance on certain computational aspects. See § 1.250(b)–1(e)(2). Similar additions are made to the reporting rules with respect to controlled foreign partnerships. See § 1.6038–3(g)(3).

V. Comments on and Revisions to Proposed § 1.250(b)–2—Qualified Business Asset Investment

A. In General

The proposed regulations provided general rules for determining the QBAI of a taxpayer for purposes of determining its DTIR, including defining QBAI, tangible property, and specified tangible property; rules regarding dual-use property; rules for determining adjusted basis; rules regarding short tax years; rules regarding property owned through a partnership; and an anti-avoidance rule. See proposed § 1.250(b)–2. Section 250(b)(2)(B) provides that QBAI, for purposes of section 250, is defined under section 951A(d), and is determined by substituting ''deduction eligible income'' for ''tested income'' and without regard to whether the corporation is a controlled foreign corporation (''CFC''). While the rules provided in § 1.951A–3 for determining QBAI of a CFC for purposes of section 951A do not apply in determining QBAI for purposes of computing the deduction of a taxpayer under section 250 for its FDII, the proposed regulations under section 250 provided a similar, but not identical, determination of QBAI for purposes of FDII.

The section 951A final regulations made certain revisions and clarifications to the proposed regulations under that section (''section 951A proposed regulations''). See § 1.951A–3. The preamble to the section 951A final regulations noted that, except as indicated with respect to the election to use a depreciation method other than the alternative depreciation system (''ADS'') for determining the adjusted basis in specified tangible property for assets placed in service before the enactment of section 951A (see part V.B of this Summary of Comments and Explanation of Revisions section), modifications similar to the revisions to proposed § 1.951A–3 will be made to proposed § 1.250(b)–2. These modifications generally clarify the QBAI computation with respect to dual-use property (§ 1.250(b)–2(d)) and partnerships (§ 1.250(b)–2(g)). Accordingly, the final regulations make conforming changes to QBAI for purposes of FDII similar to the changes made to proposed § 1.951A–3 in the section 951A final regulations. See § 1.250(b)–(2).

B. Determination of Basis Under ADS

The proposed regulations provided that, for purposes of determining QBAI, the adjusted basis in specified tangible

property is determined by using ADS under section 168(g), and by allocating the depreciation deduction with respect to such property for the taxpayer's taxable year ratably to each day during the period in the taxable year to which such depreciation relates. See section 951A(d)(3)[4] and proposed § 1.250(b)–2(e)(1). ADS applies to determine the adjusted basis in property for purposes of determining QBAI regardless of whether the property was placed in service before the enactment of section 250 or section 951A, or whether the basis in the property is determined under another depreciation method for other purposes of the Code. See section 951A(d)(3) and proposed § 1.250(b)–2(e).

A comment recommended that the final regulations for FDII should permit taxpayers the opportunity to follow U.S. GAAP for purposes of determining QBAI where the difference between U.S. GAAP and ADS is immaterial. The final regulations do not adopt this recommendation. Section 951A(d)(3) (and, by reference, section 250(b)(2)(B)) is clear that the adjusted basis in specified tangible property is determined using ADS under section 168(g). In addition, permitting taxpayers to elect to follow U.S. GAAP in the context of FDII will impose significant administrative burdens on the IRS to determine what would be immaterial and account for different depreciation methods to compute QBAI.

C. QBAI Anti-Avoidance Rule

In order to prevent artificial decreases to the DTIR amount, the proposed regulations disregarded certain transfers of specified tangible property by a domestic corporation to a related party where the corporation continues to use the property in production of gross DEI. In particular, proposed § 1.250(b)–2(h)(1) disregarded a transfer of specified tangible property by the taxpayer to a related party if, within a two-year period beginning one year before the transfer, the taxpayer leases the same or substantially similar property from a related party and such transfer and lease occur with a principal purpose of reducing the taxpayer's DTIR. In addition, a transfer or leaseback transaction was treated as per se undertaken for a principal purpose of reducing the transferor's DTIR if the transfer and leaseback each occur within a six-month span. See proposed § 1.250(b)–2(h)(3). Comments recommended that the final regulations contain a transition period for the QBAI anti-avoidance rule in proposed § 1.250(b)–2(h)(3) for transactions entered into before the date that the proposed regulations were issued. The final regulations adopt this comment. See § 1.250(b)–2(h)(5).

Another comment recommended that a taxpayer be able to rebut the presumption that a transfer or leaseback transaction was undertaken for a principal purpose of reducing the transferor's DTIR if the transfer and leaseback each occurred within a six-month span. The final regulations do not adopt this recommendation because a transfer and lease of the same or similar property that occurs between related parties within six months does not materially change the economic risk of the parties and is unlikely to be motivated by non-tax reasons. In addition, permitting taxpayers to rebut the presumption that such a transaction was undertaken for a principal purpose of reducing the transferor's DTIR creates significant administrative burdens.

VI. Comments on and Revisions to Proposed § 1.250(b)–3—FDDEI Transactions

The proposed regulations provided that FDDEI is the excess of gross FDDEI over deductions properly allocable to gross FDDEI. See proposed § 1.250(b)–1(c)(12). The proposed regulations defined gross FDDEI as the portion of a corporation's gross DEI that is derived from all of its ''FDDEI sales'' and ''FDDEI services.'' See proposed § 1.250(b)–1(c)(15). The proposed regulations defined ''sale'' to include a lease, license, exchange, or other disposition of property, including a transfer of property resulting in gain or an income inclusion under section 367. See proposed § 1.250(b)–3(b)(7).

A. Definition of ''General Property''

1. Treatment of Commodities

For purposes of determining what is a FDDEI sale (and relatedly, whether a sale is for a foreign use), the proposed regulations distinguished between ''general property'' and certain other types of property. The proposed regulations excluded any commodity (as defined in section 475(e)(2)(B) through (D)) from the definition of general property. See proposed § 1.250(b)–3(b)(3). The proposed regulations did not exclude from the definition of general property a commodity described in section 475(e)(2)(A), and therefore, the sale of such a commodity may qualify as a FDDEI sale. A comment raised a concern that the sale of a physical commodity effected through certain derivative contracts (described in section 475(e)(2)(B) through (D)) might not be treated as a sale of general property under the proposed regulations. The comment recommended clarifying that the sale of a physical commodity in satisfaction of a forward contract is not excluded from the definition of general property.

The Treasury Department and the IRS generally agree that a sale of a commodity such as an agricultural commodity or a natural resource should be a sale of general property whether it is sold pursuant to a spot contract or sold pursuant to a forward or option contract, other than a section 1256 contract or similar contract that is traded and cleared like a section 1256 contract. The sale of such a commodity through a futures or option contract that is a section 1256 contract or similar contract is not treated as a sale of general property because the interposition of a clearing organization as the counterparty to such contracts severs the connection between the original selling and buying parties to the contract such that no meaningful determination can be made whether the sale through such a contract is for a foreign use. The definition of ''general property'' in § 1.250(b)–3(b)(10) is modified accordingly. The final regulations also clarify that financial instruments or similar assets traded through futures or similar contracts do not qualify as general property.

The Treasury Department and the IRS are concerned, however, that a taxpayer could manipulate its FDDEI by selectively physically settling only its commodities forward or option contracts in which it has a gain. To prevent this manipulation, the final regulations provide that the sale of a commodity pursuant to a forward or option contract is treated as a sale of general property only to the extent that a taxpayer physically settled the contract pursuant to a consistent practice adopted for business purposes of determining whether to cash or physically settle such contracts under similar circumstances. See § 1.250(b)–3(b)(10).

The proposed regulations further provided that a sale of a security (as defined in section 475(c)(2)) or a commodity (as defined in section 475(e)(2)(B) through (D)) is not a FDDEI sale. See proposed § 1.250(b)–4(f). This rule is no longer necessary because the final regulations exclude such property from the definition of general property.

[4] As enacted, section 951A(d) contains two paragraphs designated as paragraph (3). The section 951A(d)(3) discussed in this part V.B of the Summary of Comments and Explanation of Revisions section relates to the determination of the adjusted basis in property for purposes of calculating QBAI.

2. Treatment of Interests in Partnerships

The proposed regulations did not address the conditions under which the sale of a partnership interest that is not described in section 475(c)(2) will satisfy the foreign use requirement. One comment suggested that when a taxpayer sells a partnership interest, a look-through approach should apply such that the sale of a partnership interest would be considered a sale of the partner's proportionate share in the partnership's assets. As such, the sale of the partnership interest could be considered a sale of general property and would qualify as a FDDEI sale so long as the other relevant requirements of the regulations were met. The same comment noted an alternative approach that would preclude looking through to the underlying assets and instead would require the foreign purchaser to determine if the acquisition of the partnership interest is for a foreign use.

The Treasury Department and the IRS have determined that, like an interest in a corporation (which is a security under section 475(c)(2)(A) and therefore not general property under § 1.250(b)–3(b)(10)), interests in a partnership are not the type of property that can be subject to ''any use, consumption, or disposition'' outside the United States. Furthermore, a look-through approach would be inconsistent with the fact that title to the partnership's property does not change upon the sale of an interest in a partnership and also would be difficult to administer given that the underlying property that would be tested for foreign use is not actually being transferred. Accordingly, the final regulations provide that an interest in a partnership, as well as an interest in a trust or estate, is not general property. See § 1.250(b)–3(b)(10).

3. Exclusion of Intangible Property

Under the proposed regulations, the rules applicable to the determination of whether a sale of property is for a foreign use depends on whether the property sold is ''general property'' or ''intangible property.'' See proposed § 1.250(b)–4(d) and (e). The proposed regulations defined general property as property other than intangible property, a security (as defined in section 475(c)(2)), or a commodity (as defined in section 475(e)(2)(B) through (D)). See proposed § 1.250(b)–3(b)(3). The proposed regulations defined intangible property by cross-reference to section 367(d)(4). See proposed § 1.250(b)–3(b)(4).

Two examples in the proposed regulations suggested that a limited use license of a copyrighted article is analyzed under the rules for sales of intangible property. See proposed § 1.250(b)–4(e)(4)(ii)(D) and (E) (*Example 4* and *5*). One comment recommended that if the distinction between sales of tangible and intangible property is maintained, then the final regulations should provide that software transactions involving the sale or lease of copyrighted articles are governed by the general property rules and not the intangible property rules.

The final regulations make several changes in response to this comment. Consistent with the request in the comment, the definition of ''intangible property'' for purposes of section 250 is clarified to not include a copyrighted article as defined in § 1.861–18(c)(3). See § 1.250(b)–3(b)(11). However, the rules for determining foreign use that apply to general property are not suitable for sales of digital content, including copyrighted articles, that are transferred electronically, because those rules focus on the physical transfer of property to end users. Therefore, the final regulations provide an additional rule for sales of general property that primarily contain digital content. See § 1.250(b)–4(d)(1)(ii)(D). Under the final regulations, ''digital content'' is defined as a computer program or any other content in digital format. See § 1.250(b)–3(b)(1). The determination of how a transfer of a copyrighted article is characterized (for example, as a sale or a service) for purposes of applying the final regulations is based on general U.S. tax principles, taking into account the regulations issued under section 861.[5]

Notwithstanding the final regulations' treatment of sales of copyrighted articles for purposes of determining foreign use, no inference is intended with respect to the treatment of sales of copyrighted articles under other sections of the Code. For example, the fact that a sale of a copyrighted article (or other property) is treated as a FDDEI sale does not necessarily mean that the income from the sale is foreign source under section 861.

B. Foreign Military Sales and Services

The proposed regulations provided that for purposes of section 250 a sale of property or a provision of service to the U.S. government that is governed by the Arms Export Control Act of 1976, as amended (22 U.S.C. 2751 *et. seq.*), is treated as a sale of property or provision of a service to a foreign government, and therefore may qualify as a FDDEI transaction if the other requirements under proposed §§ 1.250(b)–3 through 1.250(b)–6 are satisfied. See proposed § 1.250(b)–3(c). The proposed regulations requested comments on identifying readily available documentation sufficient to demonstrate that a particular sale or service was made pursuant to the Arms Export Control Act.

Several comments requested removal of the requirement in proposed § 1.250(b)–3(c) that the resale or on-service to a foreign government or agency or instrumentality thereof must be ''on commercial terms.'' The comments asserted that this requirement was ambiguous and observed that the taxpayer would not necessarily have access to the contract between the U.S. government and the foreign counterparty and therefore could not necessarily evaluate the commerciality of such contract. The comments also objected to the requirement that the contract between the taxpayer and the U.S. government specifically refer to the resale or on-service to the foreign government, stating that the contract may not always specify this information but that the resale or on-service could be evidenced by the taxpayer's generally available records.

In response to the preamble's request for comments on suitable documentation to demonstrate that a foreign military sale qualifies under this special rule, several comments noted that no one particular document will suffice to demonstrate that a given sale or service qualifies. Nevertheless, comments stated that ordinary course documentation should suffice to show that the sale or service qualifies. If the final regulations were to retain a list of particular documents required to demonstrate that a particular sale or service was made pursuant to the Arms Export Control Act, the comments suggested various types of documents that might be available but also stated that any list of these documents should be non-exclusive since any one document may not exist for a particular sale or service, and, in any event, the Department of Defense and the State Department modify their forms frequently. One comment asked for transitional relief for any pre-existing contracts, if the final regulations were to provide an exclusive list of required documentation. Another comment requested a presumption of foreign use in the context of foreign military sales based on the high likelihood that defense articles would satisfy foreign use—sales made pursuant to the Arms Export Control Act are limited to foreign strategic partners who intend to use

[5] See proposed § 1.861–18(a) (84 FR 40317) (adding section 250 to the list of provisions to which § 1.861–18 applies).

articles in a certain manner, such as, self-defense and internal security—and the low likelihood that a foreign person could use a defense article within the United States.

In general, the final regulations adopt the comments. Section 1.250(b)–3(c) does not include a requirement that the foreign military sale or service be ''on commercial terms'' or that the contract specifically refer to the resale or on-service to the foreign government. Instead, if a sale of property or a provision of a service is made pursuant to the Arms Export Control Act, then the sale of property or provision of a service is treated as a FDDEI sale or FDDEI service without needing to apply the general rules in § 1.250(b)–4 or § 1.250(b)–5. See § 1.250(b)–3(c). The final regulations also do not require any particular documentation to substantiate that a transaction qualifies under the rule in § 1.250(b)–3(c). Taxpayers will continue to be required to substantiate under section 6001 that any foreign military sale or service qualifies for a section 250 deduction.

C. Reliability of Documentation and Reason To Know Standard

The proposed regulations provided that to establish that a recipient is a foreign person, property is for a foreign use, or a recipient of a general service is located outside the United States, the taxpayer must obtain specific types of documentation described in proposed §§ 1.250(b)–4(c)(2), (d)(3), and (e)(3) and 1.250(b)–5(d)(3) and (e)(3). The proposed regulations also provided that the seller or renderer must not know or have reason to know that the documentation is incorrect or unreliable. Proposed § 1.250(b)–3(d)(1). One comment requested that the final regulations provide more guidance and relevant examples regarding the scope of this rule, in particular what knowledge should be imputed across a large organization and how the standard should apply when relevant information is legally protected by data privacy laws.

As described in part II of this Summary of Comments and Explanation of Revisions section, the final regulations replace the documentation requirements with substantiation rules that are more flexible with respect to the types of corroborating evidence that may be used. The knowledge or reason to know standard is retained in §§ 1.250(b)–3(f)(3) (treatment of certain loss transactions), 1.250(b)–4(c)(1) (foreign person requirement), (d)(1)(iii)(C) (general property incorporated into a product as a component) and (d)(2)(ii)(C)(*2*) (sale of intangible property consisting of a manufacturing method or process to a foreign unrelated party), and 1.250(b)–5(d)(1) (general services provided to consumers). In response to comments, the final regulations provide additional detail regarding the application of the reason to know standard in these sections. The final regulations generally provide that a taxpayer has reason to know that a transaction fails to satisfy a substantive requirement if the information that the taxpayer receives as part of the sales process contains information that indicates that the substantive requirement is not met and, after making reasonable efforts, the taxpayer cannot establish that the substantive requirement is met. See §§ 1.250(b)–3(f)(3), 1.250(b)–4(c)(1), (d)(1)(iii)(C) and (d)(2)(ii)(C)(*2*), and § 1.250(b)–5(d)(1).

D. Sales or Services to a Partnership

For purposes of determining a taxpayer's FDII attributable to sales of property or services to a partnership, the proposed regulations adopted an entity approach to partnerships. See proposed § 1.250(b)–3(g)(1). One comment suggested that if a seller of a good has a greater than 10 percent ownership interest in the recipient domestic partnership, the final regulations should also permit aggregate treatment of the partnership for this limited purpose. The comment observed that the proposed regulations do not permit sales to a domestic partnership to qualify as a FDDEI sale because a domestic partnership is not a foreign person under proposed § 1.250(b)–3(b)(2). According to the comment, in certain industries, customers request ''teaming arrangements'' that require bidders to form a single domestic bidding entity that will govern the relationship between the members of the team, but most of the work is performed by the partners, under subcontract from the partnership. The comment recommended that the practice of joint bidding should not disqualify the activity for FDII purposes.

With respect to a taxpayer's sales of property to a partnership, one comment suggested that the final regulations consider alternatives to a pure entity approach. The comment outlined two other approaches to determine if a sale to a partnership qualifies as a FDDEI sale based on whether the partnership is predominantly engaged in foreign business or a pure aggregate approach to treat the partnership as a foreign person to the extent of its ownership by direct or indirect foreign partners. With respect to a partnership engaged in multiple lines of business, each business could be viewed as a separate person for FDII purposes. While the comment did not support an aggregate approach or advocate a specific approach, the comment noted that the Treasury Department and the IRS should balance legislative intent, administrative burden, and precision.

The final regulations do not adopt these comments. The statute is clear that in the case of sales of property, the sale must be to a person that is not a United States person, and a domestic partnership is a United States person. See part VII.B of this Summary of Comments and Explanation of Revisions section. In addition, requiring taxpayers to trace the ownership, potentially through multiple tiers, of third-party partnership recipients presents significant administrative hurdles. If, alternatively, this regime were elective, it would create the potential for abuse or uneven results for similarly situated taxpayers.

E. Treatment of Certain Loss Transactions

The proposed regulations provided that if a seller or renderer knows or has reason to know that property is sold to a foreign person for a foreign use or a general service is provided to a person located outside the United States, but the seller or renderer does not satisfy the documentation requirements applicable to such sale or service, the sale of property or provision of a service is nonetheless deemed a FDDEI transaction if treating the sale or service as a FDDEI transaction would reduce a taxpayer's FDDEI. See proposed § 1.250(b)–3(f). One comment requested a clarification that taking the FDII deduction should be considered an elective action and that this rule does not impact such an election.

As described in part II of this Summary of Comments and Explanation of Revisions section, in response to comments, the final regulations adopt a more flexible approach to the FDII-specific documentation rules and instead provide specific substantiation requirements for certain elements of the regulations. Accordingly, the rule with respect to loss transactions is revised so that it only applies to transactions for which there is a specific substantiation requirement. See § 1.250(b)–3(f)(3)(i). However, the fact that § 1.250(b)–3(f)(3) has been narrowed in the final regulations does not mean that the allowed FDII deduction can be determined on a transaction-by-transaction basis. As provided in the final regulations, FDII is determined on a single aggregate basis, not on a

transaction-by-transaction basis. See § 1.250(b)–1.

The final regulations also clarify that for purposes of the loss transaction rule, whether a taxpayer has reason to know that a sale of property is to a foreign person for a foreign use, or that a general service is provided to a business recipient located outside the United States, depends on the information received as part of the sales process. If the information received as part of the sales process contains information that indicates that a sale is to a foreign person for a foreign use or that a general service is to a business recipient located outside the United States, the requisite reason to know is present unless the taxpayer can prove otherwise. See § 1.250(b)–3(f)(3)(ii). With respect to sales, the final regulations provide a non-exhaustive list of information that indicates that a recipient is a foreign person or that the sale is for a foreign use, such as a foreign address or phone number. While not all sales to a foreign person are for a foreign use (nor are all sales for a foreign use made to foreign persons), the final regulations use the same indicia for both requirements because a foreign person is more likely to make a purchase for a foreign use compared to a U.S. person. With respect to general services, information that indicates that a recipient is a business recipient include indicia of a business status, such as ''LLC'' or ''Company,'' or similar indicia under applicable law, in its name. Information that indicates that a business recipient is located outside the United States includes, but is not limited to, a foreign phone number, billing address, and evidence that the business was formed or is managed outside the United States. These rules can also apply in the case of sales made by related parties where the foreign related party is treated as the seller and the unrelated party transaction is being analyzed. See § 1.250(b)–6(c)(2).

The final regulations do not include a rule specifying that a taxpayer may choose not to claim a FDII deduction. Whether an allowable deduction must be claimed is governed by general tax principles and rules on whether such deduction can be elective is beyond the scope of these regulations.

F. Predominant Character Rule

The proposed regulations provided that if a transaction includes both a sale component and a service component, the transaction is classified according to the overall predominant character of the transaction for purposes of determining whether the transaction is subject to the FDDEI sales rules of proposed § 1.250(b)–4 or the FDDEI services rules of proposed § 1.250(b)–5. See proposed § 1.250(b)–3(e). A comment expressed support for the predominant character rule for transactions that contain both sale and service components in general but also suggested that the final regulations allow taxpayers to elect to follow U.S. GAAP accounting, which may in certain circumstances require the disaggregation of the sale and service components of a single transaction.

For purposes of simplicity and to avoid the need for complex apportionment rules, § 1.250(b)–3(d) provides a rule to determine the predominant character of the transaction when a transaction has multiple elements, such as a sale of general property and a service or sale of general property and sale of intangible property. The Treasury Department and the IRS have determined that an elective rule that allows for disaggregation would create significant complexity for taxpayers and be difficult for the IRS to administer, and could lead to whipsaw for the IRS as taxpayers elect to disaggregate when it increases the FDII deduction but not otherwise. Accordingly, the final regulations do not adopt the comment to include an election to follow U.S. GAAP to disaggregate a single transaction.

VII. Comments on and Revisions to Proposed § 1.250(b)–4—FDDEI Sales

Section 250(b)(4)(A) provides that FDDEI includes income from property the taxpayer sells to any person who is not a U.S. person and that the taxpayer establishes to the satisfaction of the Secretary is for a foreign use. Accordingly, the proposed regulations defined a FDDEI sale as a sale of property to a foreign person for a foreign use. See proposed § 1.250(b)–4(b).

A. End User Requirement

The proposed regulations provided that a sale of intangible property is for a foreign use to the extent the intangible property generates revenue from exploitation outside the United States, which is generally determined based on the location of end users purchasing products for which the intangible property was used in development, manufacture, sale, or distribution. See proposed § 1.250(b)–4(e)(2)(i).

Several comments requested that the final regulations clarify the definition of an ''end user.'' One comment recommended that an ''end user'' be defined as any consumer or business recipient that purchases a finished good for its own use or consumption (not for resale or further manufacture, assembly, or other processing). Another recommended that the finished good manufacturer or original equipment manufacturer, rather than the ultimate customer of the manufacturer, be treated as the end user.

The final regulations generally adopt the comment that the end user should be the consumer that purchases the property for its own consumption. See § 1.250(b)–3(b)(2). Further, as discussed in part VII.C.1 of this Summary of Comments and Explanation of Revisions section, the concept of an end user is also incorporated into the rules for determining whether a sale of general property, in addition to intangible property, is for a foreign use. See § 1.250–4(d). In this way, to the extent possible, the final regulations harmonize the rules for sales of general property and intangible property.

Section 1.250(b)–3(b)(2) defines the ''end user'' as the person that ultimately uses the property, and that a person who acquires property for resale or otherwise as an intermediary is not an end user. The definition of end user is modified for intangible property used in connection with the sale of general property, provision of services, sale of a manufacturing method or process intangible property, and for research and development as provided in § 1.250(b)–4(d)(2)(ii).

The final regulations do not adopt the comments that in all cases a finished goods manufacturer may be an end user. However, as described in part VII.C.7 of this Summary of Comments and Explanation of Revisions section, the final regulations continue to provide that sales of general property for manufacturing, assembly, or other processing outside the United States are sales for a foreign use. See § 1.250(b)–4(d)(1)(iii). In addition, as described in part VII.D.4 of this Summary of Comments and Explanation of Revisions section, an unrelated manufacturer (such as an original equipment manufacturer) that uses intangible property that consists of a manufacturing method or process, as provided in § 1.250(b)–4(d)(2)(ii)(C), is treated as the end user if it has purchased (or licensed) the manufacturing method or process intangible property from an unrelated party.

B. Foreign Person

The proposed regulations provided that a recipient is treated as a foreign person only if the seller obtains documentation of the recipient's foreign status and does not know or have reason to know that the recipient is not a foreign person. See proposed § 1.250(b)–4(c)(1). The proposed regulations

provided several types of permissible documentation for this purpose, such as a written statement by the recipient indicating that the recipient is a foreign person. See proposed § 1.250(b)–4(c)(2)(i).

As explained in part II of this Summary of Comments and Explanation of Revisions section, in response to comments, the final regulations remove the specific documentation requirements with respect to certain requirements, including the foreign person requirement, and further identify the substantive standards by which taxpayers must meet the requirements of the FDII regime. To address situations in which taxpayers may not be able to determine whether the recipient is a foreign person within the meaning of section 7701(a)(1), the final regulations provide that the sale of property is presumed made to a recipient that is a foreign person if the sale is as described in one of four categories: (1) Foreign retail sales; (2) sales of general property that are delivered to an address outside the United States; (3) in the case of general property that is not sold in a foreign retail sale or delivered overseas, the billing address of the recipient is outside the United States; or (4) in the case of sales of intangible property, the billing address of the recipient is outside the United States. See § 1.250(b)–4(c)(2)(i) through (iv). The presumption does not apply if the seller knows or has reason to know that the sale is to a recipient other than a foreign person. See § 1.250(b)–4(c)(1). The final regulations also specify that a seller has reason to know that a sale is to a recipient other than a foreign person if the information received as part of the sales process contains information that indicates that the recipient is not a foreign person and the seller fails to obtain evidence establishing that the recipient is in fact a foreign person. See § 1.250(b)–4(c)(1). Information that indicates that a recipient is not a foreign person includes, but is not limited to, a United States phone number, billing address, shipping address, or place of residence; and, with respect to an entity, evidence that the entity is incorporated, formed, or managed in the United States. Id.

One comment requested that the final regulations include exceptions similar to the foreign military sales rule in the proposed regulations for other sales or licenses of property through an intermediate domestic person. The comment asserted that, for various business reasons including historic relationships with unrelated parties and efficiencies from entering into global deals to sell property to unrelated parties, certain U.S. manufacturers sell products to another U.S. entity, even though that intermediary never actually takes possession, and the product is immediately resold to a foreign person and used outside the United States. In the licensing context, a U.S. taxpayer may enter a global licensing deal with another U.S. entity whereby this intermediary is granted the authority to sub-license the intangible property to its foreign affiliates. While in both cases the transactions could potentially be restructured so that the taxpayer enters into the transactions with a foreign person that is related to the U.S. intermediary, the comment suggested that unrelated counterparties could demand compensation for any restructuring. The comment also noted that the title to section 250(b)(5)(B) references rules for ''[p]roperty or services provided to domestic intermediaries,'' suggesting that Congress contemplated situations where sales to a U.S. intermediary could be treated as a sale to a non-U.S. person, although the rule itself does not reference domestic intermediaries.

As explained in the preamble to the proposed regulations, section 250(b)(4)(A)(i) requires that a sale of property (which includes licenses of intangible property) be made to a person who is not a United States person. This requirement ensures that only the domestic corporation that makes the final sale to a foreign person can claim a section 250 deduction for a FDDEI sale (rather than allowing the benefit to multiple unrelated domestic corporations that all participate in a sale). Furthermore, the Treasury Department and the IRS do not agree that the heading to section 250(b)(5)(B) implies an exception to the requirement in section 250(b)(4)(A)(i) that the sale be to a foreign person. The rule in section 250(b)(5)(B)(i) refers only to other ''persons'' and is not limited to domestic persons. In contrast, the Treasury Department and the IRS have determined that it is necessary and appropriate to provide a special rule for military sales in recognition that sales pursuant to the Arms Export Control Act are required to be made to the U.S. government, but are in effect sales to a foreign government. Therefore, the comment is not adopted.

C. Foreign Use of General Property

1. Determination of Foreign Use in General

The proposed regulations provided that the sale of general property is for a foreign use if either the property is not subject to domestic use within three years of delivery of the property or the property is subject to manufacture, assembly, or other processing outside the United States before any domestic use of the property. See proposed § 1.250(b)–4(d)(2)(i). Domestic use was defined in the proposed regulations as the use, consumption, or disposition of property within the United States, including manufacture, assembly, or other processing within the United States. See proposed § 1.250(b)–4(d)(2)(ii). In order to establish that general property is for a foreign use, the seller must generally obtain certain documentation with respect to the sale, such as proof of shipment of the property to a foreign address, and the seller cannot know or have reason to know that the property is not for a foreign use. See proposed § 1.250(b)–4(d)(1) and (3).

Several comments noted that the definition of foreign use combined with the narrow documentation requirements make it difficult for taxpayers to satisfy the foreign use requirement. Several comments interpreted the proposed regulations as requiring taxpayers to determine whether general property that was sold would actually be subject to a domestic use within three years of the date of delivery. Other comments similarly expressed confusion regarding the obligation imposed on taxpayers to determine whether there was a reason to know that property would be subject to a domestic use. One comment requested that the Treasury Department and the IRS treat certain types of sales, such as foreign retail sales at a physical store even where the consumer might ultimately use the property within the United States, as sales for foreign use.

As explained in part II of this Summary of Comments and Explanation of Revisions section, in response to comments on documentation, the final regulations take a more flexible approach to documentation and provide specific substantiation requirements for certain transactions (described in part VII.C.9 of this Summary of Comments and Explanation of Revisions section).

In addition, with respect to the requirement of ''foreign use'' for sales of general property, the final regulations clarify the meaning of that term to provide that it generally means the sale (or eventual sale) of the property to end users outside the United States or the sale of the property to a person that subjects the property to manufacture, assembly, or other processing outside the United States. See § 1.250(b)–4(d)(1)(ii) and (iii). Consistent with the recommendations from comments, the Treasury Department and the IRS have determined that a more flexible

definition of foreign use of general property that accounts for the possibility of some limited domestic use is more reasonable for taxpayers to apply and for the IRS to administer. Accordingly, the final regulations eliminate the requirement that the taxpayer have no ''reason to know'' of some domestic use for sales of general property. As described in part VII.C.2 through 8 of this Summary of Comments and Explanation of Revisions section, the final regulations generally provide that the sale of general property is for a foreign use if the seller determines that such sale is to an end user described in one of five categories. See § 1.250(b)–4(d)(1)(ii)(A)–(F).

2. Delivery of Property Outside the United States

The first category of sales that are for a foreign use is sales to a recipient that are delivered by a freight forwarder or carrier to an end user if the end user receives delivery of the general property outside the United States. See § 1.250(b)–4(d)(1)(ii)(A). The Treasury Department and the IRS have determined that, in general, if an end user receives delivery of general property outside the United States, the general property will be ''for a foreign use'' as contemplated by section 250(b)(4)(A)(ii) and additional detail regarding the actual use of the property is unnecessary. However, it would be inappropriate to treat these sales as FDDEI sales if the seller and buyer arrange for general property to be delivered to a location outside the United States only to be redelivered for use or consumption into the United States with a principal purpose of causing what would otherwise not be a FDDEI sale to be treated as a FDDEI sale. Therefore, § 1.250–4(b)(1)(ii)(A) provides an anti-abuse rule to address these concerns.

3. Location of Property Outside the United States

The second category of sales that are for a foreign use is sales of general property to an end user where the property is already located outside the United States, and includes foreign retail sales. See § 1.250(b)–4(d)(1)(ii)(B). In general, sales of general property from a foreign retail sale will be used outside the United States. While it may be possible that some end users will purchase property in a foreign retail store and use it solely within the United States, the Treasury Department and the IRS have determined that requiring a determination of the actual use of these sales would be unnecessarily burdensome.

4. Resale of Property Outside the United States

The third category of sales for a foreign use is sales to a recipient such as a distributor or retailer that will resell the general property, if the seller determines that the general property will ultimately be sold to end users outside the United States. See § 1.250(b)–4(d)(1)(ii)(C). This category is intended to apply to sales to distributors and retailers, but may also apply to other sales to foreign persons for resale. In addition, the final regulations provide that for purposes of this rule, the seller must substantiate the portion of sales to end users outside the United States under the rules described in parts II and VII.C.9 of this Summary of Comments and Explanation of Revisions section.

The proposed regulations contained alternative documentation requirements for a sale of multiple items of general property that because of their fungible nature are difficult to specifically trace to a location of use (fungible mass). See proposed § 1.250(b)–4(d)(3)(iii). Under the proposed regulations, a seller establishes foreign use of a fungible mass through market research, including statistical sampling, economic modeling and other similar methods. Id. The proposed regulations also provided that if a seller establishes that 90 percent or more of a fungible mass is for a foreign use, the entire fungible mass is treated as for a foreign use and if the seller cannot establish that 10 percent or more of the sale of a fungible mass is for a foreign use, then no part of the fungible mass is treated as for a foreign use. Id.

One comment stated that the fungible mass rules created overly stringent documentation requirements that were unnecessary, impractical, and unreliable because a U.S. seller would need to perform market research in order to meet the 90 percent threshold to qualify for foreign use. Conversely, the comment noted that a U.S. seller that could not meet the 10 percent threshold through market research could see their deduction eliminated in its entirety. The comment suggested instead a rebuttable presumption that fungible mass property sold outside the United States is for a foreign use unless a taxpayer knows or has reason to know that a material amount will be used within the United States.

In response to the comment, the final regulations eliminate the 10 percent and 90 percent thresholds and apply a proportionate rule. See § 1.250(b)–4(d)(1)(ii)(C). Under this rule, in the case of a sale of a fungible mass of general property, if a portion of the property sold is not for a foreign use, the seller may rely on the proportion of the recipient's resales of fungible mass to end users outside the United States to determine its proportion of ultimate sales to end users outside the United States. Id. In addition, the Treasury Department and the IRS have determined that prescribing specific methods such as market research, statistical sampling, economic modeling, and other similar methods to determine foreign use from the sale of a fungible mass of general property (or a sale of any general property) is unnecessary given the more flexible approach to documentation. It should be noted that market research or information from public data, such as general internet searches of secondary sources, is generally not a source of reliable information. In contrast, statistical sampling, economic modeling, or market research based on the taxpayer's own data will be more reliable.

5. Electronic Transfer of Digital Content Outside the United States

The fourth category of sales for a foreign use is for sales of digital content that are transferred electronically. Sales of digital content transferred in a physical medium are for a foreign use if described in one of the first three categories. The final regulations provide that digital content that is transferred electronically is for a foreign use if it is sold to a recipient that is an end user that downloads, installs, receives, or accesses the digital content on the end user's device outside the United States. See § 1.250(b)–4(d)(1)(ii)(D). However, if this information is unavailable, such as where the device's internet Protocol address (''IP address'') is not available or does not serve as a reliable proxy for the end user's location (for example, using a business headquarters' IP address when it has employees located both within and outside the United States who use the digital content), then the sale is for a foreign use if made to an end user with a foreign billing address, but only if the gross receipts from all sales with respect to the end user (which may be a business) are in the aggregate less than $50,000.

6. International Transportation Property

The fifth category of sales for a foreign use is sales of international transportation property. The proposed regulations provided a special rule for determining whether transportation property like aircraft, railroad rolling stock, vessels, motor vehicles or similar property that travels internationally is

sold for foreign use and therefore constitutes a FDDEI sale. See proposed § 1.250(b)–4(d)(2)(iv). Under this rule, such transportation property is sold for foreign use only if during the three-year period from the date of delivery of the property the property is located outside the United States more than 50 percent of the time and more than 50 percent of the miles traversed in the use of such property will be traversed outside the United States. The seller can establish that these criteria are satisfied by obtaining a written statement from the recipient that the property is anticipated to satisfy these tests over the requisite three-year period. See proposed § 1.250(b)–4(d)(3)(i)(A). With respect to air transportation, the proposed regulations provided that, for purposes of the above tests, international transportation property is deemed to be within the United States at all times during which it is engaged in transport between any two points within the United States, except where the transport constitutes uninterrupted international air transportation within the meaning of section 4262(c)(3) and the regulations under that section. See proposed § 1.250(b)–4(d)(2)(iv).

One comment suggested supplementing these tests with a rebuttable presumption that any foreign-registered aircraft sold to a foreign person is for foreign use. The comment observes that ''cabotage rules'' significantly restrict the use of foreign registered aircraft within the United States such that a foreign registered aircraft cannot travel between two points in the United States unless the route is part of a through trip on the way to, or coming from, a foreign destination. The comment further noted that the ability of foreign persons to register aircraft in the United States is restricted. Therefore, the comment proposed that a document evidencing foreign registration of an aircraft to a foreign person should suffice to establish foreign use.

Other comments suggested changes to the thresholds in the foreign use tests in the proposed regulations. Several comments suggested reducing the thresholds from 50 percent to 20 percent and making these tests disjunctive. Another comment would retain the 50 percent threshold but eliminate the three-year period so that the foreign use test would only have to be satisfied as of the filing date of the FDII return, and that the taxpayer be permitted to elect annually to bifurcate income from foreign and domestic use based on the percentage of actual time spent or miles traversed outside and inside the United States. A different comment suggested reducing the three-year period to one year after the date of delivery.

The Treasury Department and the IRS generally agree with the comment that place of registration is appropriate as evidence of ''use.'' Therefore, the final regulations provide that international transportation property used for compensation or hire is considered for a foreign use if it is sold to an end user that registers the property with a foreign jurisdiction. See § 1.250(b)–4(d)(1)(ii)(E). The final regulations provide that other international transportation property is considered for a foreign use if sold to an end user that registers the property with a foreign jurisdiction *and* the property is hangared or primarily stored outside the United States. See § 1.250(b)–4(d)(1)(ii)(F). This rule reflects the fact that many recipients of international transportation property will not be further using the property for the provision of international transportation services. As a result, the property will be primarily used in the place it is registered or otherwise hangared or stored. Even if such property enters the United States, because it originated in a different country, the use should not be considered domestic use because the international transportation property will generally be located outside the United States. As a result, the Treasury Department and the IRS have determined that there is no need to determine the amount of time or miles that such property is inside or outside the United States.

Finally, one comment suggested expanding the definition of transportation property to include parts of transportation property like engines, tires, electronic equipment and spare parts, even if such parts would not otherwise satisfy the foreign use tests for general property. The comment expressed concern that the sale of parts that were included within international transportation property could fail the foreign use test for general property because the parts may enter the United States as part of the transportation property. At the same time, such parts would be ineligible for the special rules for international transportation property. The comment suggested expanding the definition of transportation property to include additional parts, even if such parts would not otherwise satisfy the foreign use tests for general property.

This comment is not adopted. Such a rule would be administratively burdensome and could lead to inconsistency through the application of two sets of rules to the same transaction and property. Furthermore, the Treasury Department and the IRS have determined that the concerns that were the basis for the comment are generally addressed through the adoption of the new general rules with respect to general property and international transportation property. In particular, parts that are used outside the United States by an end user, including when incorporated into transportation property through manufacturing, assembly or other processing, would generally be considered for a foreign use under the general test for general property. As described in part VII.C.1 of this Summary of Comments and Explanation of Revisions section, this is the case even if there is the possibility of some domestic use of the property.

7. Manufacturing, Assembly, or Other Processing Outside the United States

As described in part VII.C.1 of this Summary of Comments and Explanation of Revisions section, the proposed regulations provided that the sale of general property is for a foreign use if either the property is not subject to domestic use within three years of delivery of the property or the property is subject to manufacture, assembly, or other processing outside the United States before any domestic use of the property. See proposed § 1.250(b)–4(d)(2)(i). Under the proposed regulations, general property is subject to manufacturing, assembly, or other processing only if it meets either of the following two tests: (1) There is a physical and material change to the property, or (2) the property is incorporated as a component into a second product. See proposed § 1.250(b)–4(d)(2)(iii)(A).

The proposed regulations clarified that a physical and material change does not include ''minor assembly, packaging, or labeling.'' See proposed § 1.250(b)–4(d)(2)(iii)(B). Whether property has undergone a physical and material change (as opposed to minor assembly, packaging, or labeling) is determined based on all the relevant facts and circumstances. The proposed regulations provided that general property is incorporated as a component into a second product only if the fair market value of the property when it is delivered to the recipient constitutes no more than 20 percent of the fair market value of the second product, determined when the second product is completed. See proposed § 1.250(b)–4(d)(2)(iii)(C). For purposes of this rule, the proposed regulations included an aggregation rule providing that if the seller sells multiple items of property that are incorporated into the second product, all of the property sold by the seller that is

incorporated into the second product is treated as a single item of property.

Several comments recommended that the final regulations provide more flexibility in satisfying the manufacturing, assembly, or other processing rule, especially in the context of sales to foreign unrelated parties where information to establish the two distinct tests may not be readily available. Several comments suggested that the ''physical and material change'' test should be satisfied where general property is subject to processing or manufacturing activities that are substantial in nature and that are generally considered to constitute manufacturing or production of a substantially different product. Other comments suggested that the final regulations could provide for such a ''substantial in nature'' rule as a third test in addition to the ''physical and material change'' and component tests. Comments also recommended a rebuttable presumption where a taxpayer could show that the physical and material change test had been met through reasonable documentation created in the ordinary course of its business. In addition, these comments suggested that general property sold to an unrelated party can be presumed to be sold for use, consumption, or disposition in the country of destination of the property sold, unless the taxpayer knows, or has reason to know otherwise.

With respect to the component test, comments suggested the 20 percent threshold should function as a safe harbor similar to the safe harbor under the subpart F components manufacturing rule in § 1.954–3(a)(4)(iii). Another comment suggested the addition of a facts and circumstances test. Citing concerns with lack of readily available information, comments further suggested allowing taxpayers to satisfy the 20 percent threshold through market research or other methods similar to the fungible mass rule. Another comment suggested the 20 percent threshold was too low and should be increased to 50 percent. In the case of sales of multiple components by the same seller, comments suggested that the sales should not be integrated unless actual knowledge exists as to where the products will be incorporated (such as knowledge that the product will be included in the same second product or the nature of the component compels inclusion into the second product).

Comments also noted similarities and differences with the manufacturing, assembly, or other processing requirement under FDII and the manufacturing rules under subpart F. In particular, comments pointed out that in the subpart F context, the rules address parties under common control where information is more readily available, while in the FDII context, information may not be available. A CFC's foreign base company sales income does not include income of a CFC derived in connection with the sale of personal property manufactured, produced, or constructed by such corporation. Notably, Treasury regulations provide two special manufacturing rules, often referred to as, the ''substantial transformation'' test and the ''component parts'' test. See § 1.954–3(a)(4)(ii) and (iii). Under the first test, if property is ''substantially transformed'' by the CFC before sale, the property sold is considered manufactured, produced, or constructed by the selling corporation. Under the second test, a sale of property is treated as the sale of a manufactured product, rather than the sale of component parts, if the assembly or conversion of the component parts into the final product by the selling corporation involves activities that are substantial in nature and generally considered to constitute the manufacture, production, or construction of property. A CFC is deemed to have manufactured the product if its conversion costs represent 20 percent or more of the total cost of goods sold.

In response to comments, the final regulations make several changes to the rule for manufacturing, assembly, and other processing. The final regulations clarify that general property is subject to a physical and material change if it is substantially transformed and is distinguishable from and cannot be readily returned to its original state. See § 1.250(b)–4(d)(1)(iii)(B). The final regulations also provide a separate substantive rule for the component test and retain the 20 percent threshold as a safe harbor. See § 1.250(b)–4(d)(1)(iii)(C). Under this substantive rule, general property is a component incorporated into another product if the incorporation of the general property into another product involves activities that are substantial in nature and generally considered to constitute the manufacture, assembly, or other processing of property based on all the relevant facts and circumstances. Id. The final regulations also clarify that general property is not considered a component incorporated into another product if it is subject only to packaging, repackaging, labeling, or minor assembly operations. See id. While the structure and some of the mechanics of the rule share similarities with the subpart F manufacturing component parts test, the rule is different in terms of purpose and substance.

Finally, in response to comments, the final regulations revise the safe harbor in the component test by specifying that the comparison should be between the fair market value of the property sold by the taxpayer and the fair market value of the final finished goods sold to consumers. See § 1.250(b)–4(d)(1)(iii)(C). Because some general property could be incorporated into several different finished goods, the final regulations provide that a reliable estimate of the fair market value of the finished good could include the average fair market value of a representative range of the finished goods that could incorporate the component. An example of this is provided in § 1.250(b)–4(d)(1)(v)(B)(*1*) (*Example 1*). The final regulations also modify the aggregation rule so that it applies only if the seller sells the property to the buyer and knows or has reason to know that the components will be incorporated into a single item of property (for example, where multiple components are sold as a kit). The final regulations specify that a seller has reason to know that the components will be incorporated into a single item of property if the information received as part of the sales process contains information that indicates that the components will be included in the same second product or the nature of the components compels inclusion into the second product. See § 1.250(b)–4(d)(1)(iii)(C).

8. Manufacturing, Assembly, or Other Processing in the United States

Section 250(b)(5)(B)(i) provides that if a seller sells property to another person (other than a related party) for further manufacture or other modification within the United States, the property is not treated as sold for a foreign use even if such other person subsequently uses such property for a foreign use. Section 250(b)(5)(B)(i) could apply in the case of a sale directly to a person that is a foreign person if the property is subject to further manufacture or other modification in the United States after the sale but before the property is delivered to the end user.

As described in the preamble to the proposed regulations, the proposed regulations did not contain specific rules corresponding to section 250(b)(5)(B)(i) because that rule is encompassed within the general rules relating to FDDEI sales in the proposed regulations. The proposed regulations generally provided that general property is not for a foreign use if the property

is subject to a domestic use, which includes manufacture, assembly, or other processing within the United States. See proposed § 1.250(b)–4(d)(2)(i) and (ii)(B).

Because the final regulations no longer define ''foreign use'' by reference to whether the property is subject to a domestic use, the rule in section 250(b)(5)(B)(i) is no longer encompassed within the general rules in the regulations relating to FDDEI sales. Accordingly, the final regulations include a rule that provides that if the seller sells general property to a recipient (other than a related party, for which separate rules apply) for manufacturing, assembly, or other processing within the United States, such property is not sold for a foreign use even if the requirements for foreign use are subsequently satisfied. See § 1.250(b)–4(d)(1)(iv). For consistency, the final regulations cross reference the rules described in part VII.C.7 of this Summary of Comments and Explanation of Revisions section for the meaning of ''manufacturing, assembly, or other processing.''

9. Specific Substantiation for Foreign Use of General Property

The final regulations specifically require a taxpayer to substantiate foreign use for general property for sales of general property to resellers and manufacturers. See § 1.250(b)–4(d)(3)(ii) and (iii). In the case of sales to resellers, a taxpayer must maintain and provide credible evidence upon request that the general property will ultimately be sold to end users located outside the United States. See part VII.C.4 of this Summary of Comments and Explanation of Revisions section. This requirement is satisfied if the taxpayer maintains evidence of foreign use such as the following: a binding contract that limits sales to outside of the United States, proof that the general property is suited only for a foreign market, or proof that the shipping costs would be prohibitively expensive if sold back to the United States. See § 1.250(b)–4(d)(3)(ii)(A)–(C). Certain information from the recipient or a taxpayer with corroborating evidence that credibly supports the information will also suffice. See § 1.250(b)–4(d)(3)(ii)(D)–(E). With respect to manufacturing outside the United States, the substantiation requirements are met if a taxpayer maintains proof that the property is typically not sold to end users without being subject to manufacture, assembly or other processing, obtains credible information from a recipient, or, provides a statement containing certain information with corroborating evidence. See § 1.250(b)–4(d)(3)(iii).

D. Foreign Use of Intangible Property

1. In General

The proposed regulations provided that a sale of intangible property (which includes a license or any transfer of such property in which gain or income is recognized under section 367) is for a foreign use to the extent revenue is earned from exploiting the intangible property outside the United States. See proposed § 1.250(b)–4(e)(1). Where the revenue is considered earned is generally determined based on the location of the end user. See proposed § 1.250(b)–4(e)(2). The seller of the intangible property must satisfy certain documentation requirements showing foreign use and have no knowledge, or reason to know, that the portion of the sale of the intangible property for which the seller establishes foreign use is not for foreign use. The proposed regulations also provided rules to determine foreign use for the sale of intangible property to a foreign person in exchange for periodic payments or a lump sum payment. See proposed § 1.250(b)–4(e)(2).

2. Substantiating Foreign Use of Intangible Property

Several comments recommended changes to the documentation rules. In response to those comments, and as explained in part II of this Summary of Comments and Explanation of Revisions section, the final regulations adopt a more flexible approach to documentation, but require a taxpayer to specifically substantiate foreign use for sales of intangible property. See § 1.250(b)–4(d)(3)(iv). A taxpayer must maintain and provide credible evidence upon request that a sale of intangible property will be used to earn revenue from end users located outside the United States. A taxpayer may satisfy the substantiation requirement by maintaining certain items as specified in the final regulations. See § 1.250(b)–4(d)(3)(iv). For example, a binding contract providing that the intangible property can be exploited solely outside the United States would generally satisfy the substantiation requirements demonstrating foreign use of the intangible property. See § 1.250(b)–4(d)(3)(iv)(A). Certain information from the recipient obtained or created in the ordinary course of business or corroborating evidence maintained by the taxpayer that credibly supports the information may also suffice. See § 1.250(b)–4(d)(3)(iv)(B)–(C).

3. Determining Foreign Use of Intangible Property

Comments suggested that sales with respect to intangible property be divided into several subcategories. One comment suggested dividing intangibles into production and marketing categories, with income from sales of production intangibles used in the development or manufacture of products outside the United States being FDDEI sales regardless of the location of the end user, and income from sales of marketing intangibles analyzed based on the location of the end user. Another comment suggested three subcategories of intangible sales: (i) Sales of manufacturing intangibles to foreign unrelated parties, which would be considered for a foreign use if manufacturing occurs outside the United States; (ii) sales of manufacturing intangibles to related parties, which would be considered for a foreign use if the end product is sold to a foreign person for foreign use; and (iii) sales of marketing intangibles, which would be considered for a foreign use if the end user purchases the resulting product outside the United States.

Consistent with the proposed regulations, the final regulations provide that foreign use of intangible property is determined based on revenue earned from end users located within versus outside the United States. See § 1.250(b)–4(d)(2)(i). The focus on the location of end users is derived from the requirement in section 250(b)(5)(A) that sales for a foreign use require ''use'' or ''consumption'' outside the United States and the end user is the person that ultimately consumes or uses the intangible property. In the case of legally protected intangible property (such as patents or trademarks), the location in which legal rights to the intangible property are granted and exploited generally determines the location of the end users. Therefore, for example, in the case of intangible property such as patents that provide rights only for markets outside the United States, the end users will generally be located solely outside the United States. In the case of intangible property that allows for worldwide exploitation (or intangible property that is not legally protected), a more specific determination of end users will generally be necessary to determine the portion of intangible property income that is for a foreign use versus not for a foreign use.

In response to the comments received, the final regulations provide more detailed guidance on determining where

revenue is earned from end users of the intangible property, including rules for intangible property embedded in general property or used in connection with the sale of general property, intangible property used to provide services, and intangible property used in research and development. See § 1.250(b)–4(d)(2)(ii). The final regulations also include rules for determining revenue earned from sales of a manufacturing method or process, which is similar to the separate rule for ''production intangibles'' or ''manufacturing intangibles'' that was suggested by comments.

Revenue is generally earned from intangible property used to manufacture products or provide services through sales of such products or services, or from limited use licenses of the intangible property, whether those sales, services, or limited use licenses are executed by an owner, licensee, or sub-licensee of the intangible property. Until revenue is earned from sales, services, or limited-use licenses to the end user that ultimately consumes the property or receives the service, the intangible property is generally not ''exploited.'' Consistent with this view, the final regulations generally place the location of use of the intangible property with the location of the end user, which is generally the person who ultimately uses the general property in which the intangible property is embedded or associated with, or, if the intangible property is used to provide a service, the service recipient. See § 1.250(b)–4(d)(2)(ii)(A) and (B). These rules provide the same determination of location of end user for sales or licenses of intangible property used in research and development. See § 1.250(b)–4(d)(2)(ii)(D).

4. Intangible Property Used in Manufacturing

The preamble to the proposed regulations requested comments regarding whether to adopt a rule for intangible property similar to proposed § 1.250(b)–4(d)(2)(i)(B) (treating a sale of general property as for a foreign use if the property is subject to manufacturing, assembly, or other processing outside the United States). Several comments supported a rule that treats the sale of intangible property as for a foreign use where intangibles are used in manufacturing that takes place outside the United States. Some of the comments also suggested that footnote 1522 of the Conference Report to the Act supported this position because that footnote did not specify that its application is limited to only tangible property that is subject to manufacturing, assembling, or other processing outside the United States.[6]

Based on comments received, the final regulations provide a special rule for sales to a foreign unrelated party of a manufacturing method or process or for know-how used to put the manufacturing method or process to use in manufacturing (the ''manufacturing method or process rule''). See § 1.250(b)–4(d)(2)(ii)(C). The final regulations provide that when this rule applies, then the foreign unrelated party is treated as an end user located outside the United States, unless the seller knows or has reason to know that the manufacturing method or process will be used in the United States, in which case the foreign unrelated party is treated as an end user located within the United States. For purposes of this rule, reason to know is determined based on the information received from the recipient during the sales process. See § 1.250(b)–4(d)(2)(ii)(C)(*1*).

The manufacturing method or process rule does not apply to sales or licenses of a manufacturing method or process to an unrelated foreign party for purposes of manufacturing products for or on behalf of the seller of the manufacturing method or process or any of the seller's affiliates. See § 1.250(b)–4(d)(2)(ii)(C)(*2*). Applying the manufacturing method or process rule to determine the end user with respect to such an arrangement, such as a contract or toll manufacturing arrangement, is not appropriate because the seller or related party to the seller is using the manufacturing method or process in manufacturing for itself. Such use by the seller is effectively a circular transfer of the intangible property back to the seller. However, the sale of the manufactured products by the seller of the manufacturing method or process or the seller's affiliates can still qualify as a FDDEI sale under other provisions such as § 1.250(b)–4(d)(1)(ii).

The manufacturing method or process rule applies only to certain types of intangibles that are used in the manufacturing process. The distinction between the types of intangibles that qualify for this rule and other types of intangibles that may be used by manufacturers is based on a distinction between use of a patented method or process and use of other types of patented items. In all other cases, the foreign use of intangible property is determined based on revenue earned from end users located within versus outside the United States.

The manufacturing method or process rule applies only to sales to unrelated parties (including sales made through related parties that ultimately result in a sale of the manufacturing method or process to an unrelated party). Section 250(b)(5)(C) provides that sales to related parties are treated as for a foreign use only if the property is ultimately sold or used in connection with property that is sold to an unrelated party who is not a United States person. While § 1.250(b)–6(c) gives effect to this rule by providing special rules for sales of general property to related parties (which apply in the case of sales of property to related parties for further manufacturing), those rules do not apply to sales of intangible property. Under the proposed regulations, a related party rule was not needed for sales of intangible property, including property consisting of a manufacturing method or process, because the proposed regulations generally provided that intangible property used in the manufacture of a product is treated as exploited at the location of the end user when the product is sold to the end user. Proposed § 1.250(b)–4(e)(2)(i). Under the final regulations, limiting the manufacturing method or process rule to unrelated party sales serves the purpose of ensuring that such sales are FDDEI sales only to the extent contemplated by section 250(b)(5)(C). For example, if the taxpayer sells to a foreign related party a manufacturing method used to produce general property, then the sale of the manufacturing method is for a foreign use to the extent that the foreign related party's sales of the general property are for a foreign use under the rules applicable to sales of general property. See § 1.250(b)–4(d)(2)(ii)(A). This result is generally consistent with the result if the related party sale had instead been of general property that was used in manufacturing.

5. Bundled Intangible Property

One comment requested that where a taxpayer licenses a bundle of intangibles, it should be allowed to elect the application of the potentially applicable rules based either on the predominant feature of the bundle or using any reasonable method. The Treasury Department and the IRS recognize that intangible property is sometimes sold or licensed as a bundle, such as the license of patents, copyrights, trademarks, tradenames, and

[6] See H. Rept. 115–466, at 625, fn. 1522 (2017) (Conf. Rept.) (''If property is sold by a taxpayer to a person who is not a U.S. person, and after such sale the property is subject to manufacture, assembly, or other processing (including the incorporation of such property, as a component, into a second product by means of production, manufacture, or assembly) outside the United States by such person, then the property is for a foreign use.'').

know-how in a single transaction, without specifying the amount of payment required for each item of intangible property. The final regulations provide for a predominant character determination when a transaction has multiple elements, such as a service and sale or a sale of general property and intangible property, to determine whether to apply the provisions for sales of general property, sales of intangible property, or the provision of services. See § 1.250(b)–3(d).

In the case of a sale or license of bundled intangible property, the final regulations will generally base the location of exploitation on the location of the end user who ultimately uses the general property in which the intangible property is embedded or associated with, or, if the intangible property is used to provide a service, the location of the service recipient. See § 1.250(b)–4(d)(2)(ii)(A)–(B), (D). Only in an unrelated party transaction involving the manufacturing method or process rule will the end user location be determined differently than a transaction involving intangible property used with general property, services, or research and development. However, the manufacturing method or process rule does not determine the location of the end user of other intangible property bundled with the manufacturing method or process. As a result, the final regulations do not provide for an election to treat or characterize the sale or license of bundled intangible property that includes manufacturing method or process intangibles as well as other intangible property as falling entirely within one of the categories of intangible property specified in § 1.250(b)–4(d)(2).

6. Treatment of Product Intangibles as Components

One comment suggested that the final regulations include a rule that would treat certain ''product intangibles'' as a component of the finished product and provide a rule that is analogous to the rule for sales of general property that is incorporated as a component of another product outside the United States. See § 1.250(b)–4(d)(1)(iii)(A) and (C). The final regulations do not adopt this comment. Intangible property has no physical properties, and therefore cannot be incorporated into a finished good or otherwise be a ''component'' of the finished good in the same way as items of general property that are considered to be components. See section 367(d)(4) (defining intangible property). For example, a patent on an article of manufacture is not a component of the finished product protected by the patent. Similarly, while a trademark design may be placed on a component of a finished product, the trademark itself is not a component of the finished product. Therefore, the final regulations do not provide a component rule for the sale or license of intangible property. Instead, the general rule that use is determined based on where the intangible property is exploited applies to these types of sales.

7. Intangible Property Used To Enhance Other Intangible Property

One comment discussed intangibles that are sold to an unrelated foreign person who enhances the intangible (for example, by adapting it to local markets) or uses the intangible property to develop other intangible property and subsequently sells such enhanced or newly created intangible property outside the United States. In these situations, the comment recommended that the sale of the original intangible property should be presumed to be for foreign use if the location of the research and development is outside the United States and the recipient is unrelated to the original seller, and suggested that footnote 1522 of the Conference Report supports such a rule.

The final regulations do not adopt the comment. As discussed in part VII.D.3 of this Summary of Comments and Explanation of Revisions section, revenue is generally earned from intangible property used to manufacture products or provide services through sales of such products or services, or from limited use licenses of the intangible property, whether those sales, services, or limited use licenses are executed by an owner, licensee, or sub-licensee of the intangible property. Until revenue is earned from sales, services, or limited-use licenses to the end user that ultimately consumes the property or receives the service, the intangible property is generally not ''exploited.'' Although the final regulations provide a limited exception from this end user requirement for intangible property that consists of a manufacturing method or process (see part VII.D.4 of this Summary of Comments and Explanation of Revisions section), no exception is included for intangible property used to enhance or create other intangible property. The Treasury Department and the IRS have determined that the activities described in the comment do not constitute ''use'' by end users but rather are intermediate steps in the development of the intangible property before being exploited and used. In addition, nothing in the text of section 250 or footnote 1522 of the Conference Report suggests that a different definition of foreign use should apply in the case of research and development.

However, in response to comments, the final regulations clarify the rule for sales of intangible property used to develop other intangible property or to modify existing intangible property. See § 1.250(b)–4(d)(2)(ii)(D). In such a case, the end user of the intangible property (primary IP) used to develop other intangible property or to modify existing intangible property (secondary IP) is the end user of the property in which the secondary IP is embedded. If the secondary IP is used to provide a service, the end user is the unrelated party recipient. If the secondary IP qualifies as a manufacturing method or process (as described in part VII.D.4 of this Summary of Comments and Explanation of Revisions section), then the rules applicable to sales of a manufacturing method or process apply to determine if the sale of the secondary IP is for a foreign use. See § 1.250(b)–4(d)(2)(ii)(C).

8. Intangible Property Used To Provide Services

One comment noted that intangible property may be sold to recipients that provide services, rather than solely to recipients that manufacture and sell goods, and that the proposed regulations did not specifically address the sale of intangible property used to provide services. For such sales, the comment recommended that the intangible property be treated as exploited in the locations in which the recipient receives legal rights to the intangible property under the terms of the contract or other applicable law. Another comment recommended that for sales of intangible property to unrelated persons for use in the provision of services, the sales should be presumed to be for foreign use if the services will be performed outside the United States without regard to the location of the person or persons receiving such services.

Revenue may be earned from intangible property through the provision of services, but until that revenue is earned, the intangible property is generally not used or ''exploited.'' Consistent with this view, the final regulations generally place the location of use of the intangible property with the location of the end user, which in the case of intangible property used to provide a service, is the service recipient. See § 1.250(b)–4(d)(2). These rules are generally consistent with the location in which legal rights to the intangible property

are granted and exploited, with exploitation generally being located where the end user ultimately consumes the property or the services the intangible property is used to provide. See § 1.250(b)–4(d)(2)(i). The rules in § 1.250(b)–5 for FDDEI services generally apply for purposes of determining the location of the end user. Therefore, for example, the location of the end user of intangible property that is used to provide advertising services is determined based on the location of the individuals viewing the advertisements. See § 1.250(b)–5(e)(2)(ii).

However, the regulations do not provide a presumption that a sale to a foreign unrelated party that uses that intangible property to provide services outside the United States is presumed to be for foreign use. Such a presumption could produce results that would be inconsistent with the general approach for determining the location of use of intangible property by reference to the location of exploitation (which, in the case of intangible property used to provide services, is generally the location of the person or persons receiving such services), and the Treasury Department and the IRS have determined that a departure is not warranted in this case.

9. Determination of Revenue

The proposed regulations provided that when intangible property is sold in exchange for periodic payments, the extent to which the sale qualifies for a foreign use is made annually based on actual revenue earned by the recipient. Proposed § 1.250(b)–4(e)(2)(ii). In the case of a sale of intangible property in exchange for a lump sum payment, the extent to which the sale qualifies for foreign use is determined based on the ratio of total net present value the seller would have reasonably expected to earn from exploiting the intangible property outside the United States to total net present value the seller reasonably expected to earn from exploiting the intangible property worldwide. Proposed § 1.250(b)–4(e)(2)(iii). However, for purposes of satisfying the documentation requirements, the proposed regulations provided that in the case of sales in exchange for periodic payments that are not contingent on the revenue or profit of a foreign unrelated party, a taxpayer may establish the extent to which a sale of intangible property is for a foreign use using the principles applicable to sales in exchange for a lump sum payment, except that the taxpayer must make projections on an annual basis. See proposed § 1.250(b)–4(d)(3)(ii). This rule recognized that if the recipient of the intangible property makes periodic payments that are not contingent on the recipient's sales or revenue, the recipient may not be willing to provide information about the end users of the intangible property.

a. Periodic Payments

Like the proposed regulations, the final regulations provide that for periodic payments (such as annual royalty payments or fixed installment payments) in exchange for rights to intangible property, other than intangible property consisting of a manufacturing method or process that is sold to a foreign unrelated party, taxpayers may estimate revenue earned by unrelated party recipients from any use of the intangible property based on the principles for determining revenue from lump sum sales, if actual revenue earned by the foreign party cannot be obtained after reasonable efforts. See § 1.250(b)–4(d)(2)(iii)(A). While the proposed regulations required estimated revenue to be determined on an annual basis when a taxpayer relies on this rule, the final regulations eliminate this requirement. The Treasury Department and the IRS have determined that when estimated revenue earned by unrelated party recipients must be used, information available at the time of the sale will be more reliable than information available subsequently. In addition, eliminating the requirement to determine estimated revenue annually reduces the administrative burden on the taxpayer. See § 1.250(b)–4(d)(2)(iii)(A).

b. Lump Sum Payments

One comment recommended that the seller be allowed to use revenue the recipient (rather than the seller) earns or expects to earn from use of the intangible property to determine the extent to which a sale of intangible property in exchange for a lump sum payment qualifies for foreign use because using the recipient's expected or actual revenue is more accurate for determining foreign use. The comment acknowledges the administrative difficulty inherent in determining foreign use in the case of sales of intangible property for a lump sum payment and in obtaining actual or expected revenue data from the recipient.

In response to the comment, the final regulations allow taxpayers to use net present values using reliable inputs, which may include net present values of revenue that the recipient expected to earn from the exploitation of the intangible property within and outside the United States if the seller obtained such revenue data from the recipient near the time of the sale and such revenue data was used to negotiate the lump sum price paid for the intangible property. See § 1.250(b)–4(d)(2)(iii)(B). In determining whether such inputs are reliable, the extent to which the inputs are used by the parties to determine the sales price agreed to between the seller and a foreign unrelated party purchasing the intangible property will be a factor. The final regulations do not allow for use of actual revenue earned by the recipient from the use of the intangible property in a lump sum sale because actual revenue earned by the recipient for all the years the recipient uses the intangible property will not be known when the seller files its tax return for the tax year in which the sale of the intangible property occurred.

c. Payments for Manufacturing Method or Process

With respect to sales to a foreign unrelated party of intangible property consisting of a manufacturing method or process, the final regulations provide that the revenue earned from the end user is equal to the amount received from the recipient in exchange for the manufacturing method or process. See § 1.250(b)–4(d)(2)(iii)(C). In the case of a bundled sale of intangible property consisting of a manufacturing method or process and other intangible property, the value of the manufacturing method or process relative to the total value of the intangible property must be determined using the principles of section 482.

E. Treatment of Certain Hedging Transactions

Several comments recommended that gain or loss from certain hedging transactions with respect to commodities be considered gain or loss from sales of general property. In support, the comments noted that the Federal income tax treatment of certain hedging transactions (for example, character and timing) corresponds to the treatment of the underlying physical transaction. Comments noted that these rules exist, in part, because the combined value of the hedging transaction and the underlying physical transaction generally reflects a taxpayer's true economic exposure to the underlying physical commodity. Consistent with that approach and rationale, these comments recommended a similar approach for purposes of determining FDDEI sales income.

The Treasury Department and the IRS agree that certain hedging transactions

should be treated in a manner that is similar to the treatment of the commodities hedged by those transactions. Furthermore, the Treasury Department and the IRS have determined that the adjustment for qualified hedging transactions should apply to all general property, rather than only commodities. Hedges of property other than commodities have the same economic effect as hedges of commodities, such that the rationale for determining FDDEI sales income from hedges by reference to hedges of commodities applies equally to other types of property. Accordingly, the final regulations generally provide that a corporation's or partnership's gross income resulting from FDDEI sales of general property is adjusted by reference to certain hedging transactions. See § 1.250(b)–4(f). The hedging transaction must meet the requirements of § 1.1221–2, including the identification requirement under § 1.1221–2(f), the transaction must hedge price risk or currency fluctuation with respect to ordinary property, and the property being hedged must be general property that is sold in a FDDEI sale. The Treasury Department and the IRS are considering issuing more detailed guidance on hedging transactions in the form of future proposed regulations. Comments are requested on this topic.

VIII. Comments on and Revisions to Proposed § 1.250(b)–5—FDDEI Services

Section 250(b)(4)(B) provides that FDDEI includes income from services provided by a domestic corporation to any person, or with respect to property, not located within the United States. Section 250 does not prescribe rules for determining whether a person or property is ''not located within the United States.'' Accordingly, proposed § 1.250(b)–5 provided rules for determining whether a service is provided to a person, or with respect to property, located outside the United States.

A. Categories of Services

The proposed regulations separated all services into five mutually exclusive and comprehensive categories: general services provided to consumers, general services provided to business recipients, proximate services, property services, and transportation services. See proposed § 1.250(b)–5(b). Whether a service is a FDDEI service is determined under the rules relevant to the applicable category.

One comment requested that the final regulations address how ''digital services'' are treated and classified under the FDDEI services regulations, although no recommendation was provided. Another comment requested more guidance on the application of the rules for general services to business recipients in the software-as-a-service context.

In response to these comments, the final regulations provide additional guidance, as described in parts VIII.B.1 and VIII.B.2.c of this Summary of Comments and Explanation of Revisions section, with respect to services that are ''electronically supplied.'' Services that are provided electronically typically will be categorized as general services because they will not meet the definitions of proximate services, property services, or transportation services. To provide additional guidance for determining the location of the recipients of services that are electronically supplied, the final regulations create a new category of general services defined as ''electronically supplied services,'' which includes general services (other than advertising services, described in the following sentence) that are delivered over the internet or an electronic network. See § 1.250(b)–5(c)(5). In addition, the final regulations create a new subcategory of general services for advertising services, including advertising services to display content via the internet, and provide additional guidance with respect to these services as described in part VIII.B.2.c of this Summary of Comments and Explanation of Revisions section. See § 1.250(b)–5(c)(1).

B. General Services

1. General Services Provided to Consumers

The proposed regulations provided that a consumer is located where the consumer resides when the service is provided and required documentation to establish the place of residence. See proposed § 1.250(b)–5(d)(2) and (3). Special rules for small transactions or small taxpayers allowed the taxpayer to establish the consumer's location using the taxpayer's billing address for the consumer. See proposed § 1.250(b)–5(d)(3)(ii).

Comments suggested that rather than limiting taxpayers to a finite list of documentation, the rules should allow taxpayers to support the status of the consumer as a person located outside the United States using documentation that is collected in the ordinary course of the taxpayer's trade or business.

As discussed in part II of this Summary of Comments and Explanation of Revisions section, the final regulations adopt a more flexible approach to documentation requirements compared to the proposed regulations. While the final regulations include specific substantiation requirements for certain elements of the regulations, no such rules are provided for general services to consumers. Furthermore, to minimize the burden associated with determining the residence of consumers, the final regulations provide that if the renderer does not have (or cannot after reasonable efforts obtain) the consumer's location of residence when the service is provided, the consumer of a general service is treated as residing outside the United States if the consumer's billing address is outside of the United States. See § 1.250(b)–5(d)(1). However, this rule does not apply if the renderer knows or has reason to know that the consumer does not reside outside the United States. The final regulations clarify that ''reason to know'' is determined based only on whether the information received as part of the provision of the service contains information that indicates that the consumer resides in the United States. Because this rule applies to all services provided to consumers (with the modification for electronically supplied services described in the next paragraph), the final regulations do not provide a special rule for small transactions or small taxpayers.

With respect to electronically supplied services that are provided to consumers, the final regulations provide that the consumer is deemed to reside at the location of the device used to receive the service, which may be an IP address, if available. However, if the renderer cannot determine the location of that device after reasonable efforts, the general rule based on billing address applies, subject to the renderer not knowing or having reason to know that the consumer does not reside outside the United States.

2. General Services Provided to Business Recipients

The proposed regulations determined the location of a business recipient based on the location of its operations, and the operations of any related party of the recipient, that receive a benefit (as defined in § 1.482–9(l)(3)) from such service. See proposed § 1.250(b)–5(e)(2) and (4). The proposed regulations provided that a service is generally provided to a business recipient located outside the United States to the extent that the renderer's gross income from providing the service is allocated to the business recipient's operations outside the United States. See proposed § 1.250(b)–5(e)(2)(i). Where the service

confers a benefit on the operations of the business recipient in specific locations, the proposed regulations provided that gross income of the renderer is allocated based on the location of the operations in specific locations that receive the benefit. See proposed § 1.250(b)–5(e)(2)(i)(A). Where a service confers a benefit on the recipient's business as a whole, or where reliable information about the particular portion of the operations that specifically receive a benefit from the service is unavailable, the proposed regulations provided that the service is deemed to confer a benefit on all of the business recipient's operations. See proposed § 1.250(b)–5(e)(2)(i)(A). For purposes of this rule, a business recipient is treated as having operations in any location where it maintains an office or other fixed place of business. See proposed § 1.250(b)–5(e)(2)(ii). The proposed regulations also required a taxpayer to obtain documentation sufficient to establish the location of a business recipient's operations that benefit from the service. See proposed § 1.250(b)–5(e)(1) and (3). Under the proposed regulations, special rules for small transactions or small taxpayers allowed the taxpayer to establish the consumer's location using the taxpayer's billing address for the consumer. See proposed § 1.250(b)–5(e)(3)(ii).

a. Operations of a Business Recipient of General Services

Several comments requested clarification regarding the definition of a business recipient's operations. Some comments requested that the rule be expanded to include operations performed outside of the locations where the business recipient maintains an office or other fixed place of business. For example, where business recipients operate satellites or vessels, the comment suggested that business recipients should be treated as having operations at the location of the satellite or vessel.

The location of a business recipient's operations that benefit from a general service is based on the geographical location where the business recipient's activities are regular and continuous and is not based on the current location of mobile property such as satellites or vessels. Moreover, as noted in the next paragraph, the final regulations clarify that an office or other fixed place of business is a fixed facility through which the business recipient engages in a trade or business. See § 1.250(b)–5(e)(3)(i). In the case of services performed with respect to a satellite, the location of the business recipient that receives services with respect to the satellite is based on where the business recipient remotely performs activities with respect to the satellite (which could be within the United States or in a foreign country), rather than in space. In addition, services performed with respect to a vessel owned by a business recipient may qualify as proximate services or property services, depending on the nature of the services. Therefore, no further changes to the regulations are necessary to respond to the comment.

One comment requested further clarification of the term ''fixed place of business,'' such as whether it has the same meaning as it does for section 864(c) purposes. The comment did not specify whether using the meaning that the term has for section 864(c) purposes would be appropriate. However, the Treasury Department and the IRS have determined that it would not be appropriate to adopt the definition that applies for purposes of section 864(c). Because the final regulations define a business recipient as including all related parties of the recipient, whereas section 864(c) applies on a taxpayer-by-taxpayer basis, adopting the definition of an office or other fixed place of business that is in § 1.864–7 would cause confusion. However, the final regulations clarify that an office or other fixed place of business is a fixed facility, that is, a place, site, structure, or other similar facility, through which the business recipient engages in a trade or business. See § 1.250(b)–5(e)(3)(i). In addition, the final regulations provide that for purposes of determining the location of the business recipient, the renderer may make reasonable assumptions based on the information available to it. The Treasury Department and the IRS recognize that taxpayers may not be able to obtain precise information about unrelated business recipients; therefore, the final regulations allow taxpayers to make reliable assumptions based on the information available to them. See id.

One comment requested guidance on how to determine the location of operations of a business recipient that does not have an office or fixed place of business. As an example, this could occur when the business recipient is a partnership that does not itself have any offices or employees but is managed by one or more of its partners. The comment suggested that in these circumstances, the final regulations presume that the business recipient has operations where it is formed or incorporated.

To address this comment, the final regulations provide that if the business recipient does not have an identifiable office or fixed place of business (including the office of a principal manager or managing owner), the business recipient is deemed to be located at its primary billing address. See § 1.250(b)–5(e)(3)(iii). The Treasury Department and the IRS considered using place of formation or place of incorporation, but determined that a business recipient's billing address is generally available to the renderer and often bears a closer connection to the business recipient's location of actual operations.

Finally, for the sake of concision, the final regulations expand the definition of a ''business recipient'' to include all related parties (as defined in § 1.250(b)–1(c)(19)) of the recipient. Compare § 1.250(b)–5(c)(3) with proposed § 1.250(b)–5(e)(4) (the latter providing, in a separate paragraph, that a reference to a business recipient includes a reference to any related party of the business recipient). However, to avoid circularity in circumstances where the business recipient is a related party of the taxpayer, in these circumstances, the term ''business recipient'' does not include the taxpayer. See § 1.250(b)–5(c)(3).

b. The Meaning of ''Benefit''

One comment expressed concern that the proposed regulations' reliance on the principles of § 1.482–9(l)(3), which explains when an activity is considered to provide a ''benefit'' to a recipient, would be difficult to apply outside the related party context because the renderer may not have the information necessary to perform a detailed analysis of the recipient's operations. The comment suggests that transfer pricing standards should not be applied to evaluate transactions for purposes of section 250. The comment suggested that the term ''benefit'' should retain the reference to § 1.482–9(l)(3), but that the regulations should include a presumption that a general service provided to a foreign person benefits operations located outside the United States.

The Treasury Department and the IRS do not intend that the reference to § 1.482–9(l)(3) in the definition of ''benefit'' be interpreted as suggesting that taxpayers are required to perform a transfer pricing-like analysis of the recipient's operations. Rather, the reference is intended to clarify, using a concept that is based on existing tax principles, that a service confers a benefit on operations of a recipient only if an uncontrolled party with similar operations would pay for the service under comparable circumstances. For example, if a service benefits particular operations of a business recipient so

indirectly or remotely that an unrelated party with similar operations would not pay for the service, the service does not confer a benefit on those operations. See § 1.482–9(l)(3)(ii). Accordingly, the final regulations retain the reference to § 1.482–9(l)(3) in defining ''benefit.''

One comment also requested clarification regarding the types of benefits that must be considered in determining the location of the business recipient of a general service. The comment gives the example of a U.S. financial advisor providing advice to a foreign parent that is expected to increase the value of the foreign parent's publicly traded stock, which would also benefit any U.S. subsidiaries by making their equity-based compensation more valuable. The implication of the comment is that it is unclear whether the U.S. subsidiaries receive a compensable benefit from the service provided because their employees are also shareholders of the foreign parent.

As noted, the reference to § 1.482–9(l)(3) in the definition of ''benefit'' is intended to provide clarity on the meaning of ''benefit'' using a concept that is based on existing tax principles. As described in the previous paragraph, under § 1.482–9(l)(3)(ii), an activity is not considered to provide a ''benefit'' within the meaning of § 1.482–9(l)(3) if the benefit to the recipient is ''so indirect or remote'' that the recipient would not be willing to pay an uncontrolled party to perform a similar activity. Accordingly, in fact patterns such as the one described in the comment (where the service potentially confers a benefit on a related party of the recipient if the employees of the related party are also shareholders of the recipient), taxpayers must determine whether a related party with employees that are shareholders of a company would generally pay a financial advisor to provide advice to the company or whether the benefit to the related party is too indirect or remote. Section 1.482–9(l) provides comprehensive guidance, including twenty-one examples, to assist taxpayers in understanding when an activity is considered to confer a benefit on a party other than the direct recipient. Accordingly, the comment is not adopted.

c. Determining the Locations of the Business Recipient's Operations That Benefit From General Services

Several comments addressed the proposed regulations' rule for determining the location of the recipient of general services that benefits from the service. See proposed § 1.250(b)–5(e)(2). One comment suggested that the final regulations include language included in the preamble to the proposed regulations stating that for purposes of this rule, ''the location of residence, incorporation, or formation of a business recipient is not relevant.'' The final regulations adopt this comment. See § 1.250(b)–5(e)(1).

Several comments indicated that it would be difficult, if not impossible, for taxpayers to obtain information regarding which of a business recipient's locations benefits from a service. While the proposed regulations allowed taxpayers in these circumstances to assume that the services will benefit all of the business recipient's operations ratably, several comments suggested that this simplification was not sufficient. Several comments stated that these difficulties could be alleviated by making the transition rule in proposed § 1.250–1(b) permanent or by making the rules applicable to small businesses and small transactions available to all taxpayers. Several comments requested that the final regulations incorporate certain presumptions to simplify the rule, such as a presumption that any operations of the service recipient that are not known to be (or identifiable as) within the United States are presumed foreign or that services provided to a foreign person are presumed to benefit operations located outside the United States.

The final regulations retain the same general approach as the proposed regulations for determining the location of the business recipient, with some revisions for concision, by providing that a service is provided to a business recipient located outside the United States to the extent that the service confers a benefit on operations of the business recipient that are located outside the United States. See § 1.250(b)–5(e)(1). Like the proposed regulations, the final regulations provide that the determination of which operations of the business recipient benefit from a general service is made under the principles of § 1.482–9. Further, the final regulations clarify that in applying these principles, (1) the taxpayer, (2) the portions of the business recipient's operations within the United States (if any) that may benefit from the general service, and (3) the portions of the business recipient's operations outside the United States that may benefit from the general service, are treated as if they are each one or more controlled taxpayers.

For purposes of applying the principles of § 1.482–9, the final regulations provide taxpayers with flexibility to determine the extent to which a business recipient's operations within or outside of the United States are treated as one or more separate controlled taxpayers, given that taxpayers generally will not have complete information regarding the operations of the business recipient. Any reasonable method can be used for determining the set and scope of business recipient operations that are treated as separate controlled taxpayers, for example, by segregating the operations on a per entity or per country basis, or by aggregating all of the business recipient's operations outside the United States as one controlled taxpayer. For example, if a business recipient has operations in the United States, Country X, and Country Y, all of which may benefit from the taxpayer's services, the business recipient's operations in the United States, Country X, and Country Y may each be treated as separate controlled taxpayers. Alternatively, the business recipient's operations in the United States, and the business recipient's combined operations in Country X and Country Y, could be treated as two separate controlled taxpayers. The amount of the benefit conferred on each of the business recipient's operations is determined under the principles of § 1.482–9(k).

To simplify the rule, the final regulations remove the provision stating that if a service benefits all of the business recipient's operations, gross income of the renderer is allocated ratably to all of the business locations of the recipient, as that provision was redundant of the general rule. The final regulations also remove the provision that gross income of the renderer is allocated ratably to all of the business locations of the recipient if the renderer is unable to obtain reliable information regarding the specific locations of the operations of the business recipient to which a benefit is conferred. The Treasury Department and the IRS have determined that it would be inappropriate to allow a deduction that is not based on reliable information.

Comments also suggested that the final regulations should define foreign operations by negation such that a service is considered provided to a business recipient outside the United States if that service is not provided to a business recipient inside the United States. These comments asserted that this would allow mobile activity performed in outer space, international airspace, or international water to qualify as FDDEI services. The Treasury Department and the IRS have determined that evidence that services do not benefit a business recipient's operations within the United States is

equivalent to demonstrating that the service benefits operations outside the United States. Therefore, no changes to the regulations are necessary. However, as explained in part VIII.B.2.a of this Summary of Comments and Explanation of Revisions section, the location of a business recipient's operations is determined based on whether its activities are regular and continuous in a particular geographical location, which generally would not include activities in outer space or international space, but may include international water (for example, in the case of a drilling rig).

Several comments requested clarity on how to determine the location of operations that benefit from general services in the case of services that are electronically supplied. In response, the final regulations modify the general rule for determining the location of the business recipient of electronically supplied services and advertising services so that location will be determined based on information that will generally be available to renderers of those types of services. See § 1.250(b)–5(e)(2)(ii) and (iii).

Advertising services are different from other general services: The renderer will generally be able to determine where the advertisements are viewed because the renderer controls where the advertisements are displayed. The Treasury Department and the IRS have determined that where the advertisement is viewed serves as a reliable proxy for the locations of the business recipient that benefit from the service. Generally, it will be in the business recipient's best interest to advertise its products or services in the locations where it does business. Therefore, the final regulations provide that with respect to advertising services, the operations of the business recipient that benefit from the advertising service are deemed to be located where the advertisements are viewed by individuals. See § 1.250(b)–5(e)(2)(ii). The final regulations further provide that if advertising services are displayed via the internet, the advertising services are viewed at the location of the device on which the advertisements are viewed. See id. For this purpose, the IP address may be used to establish the location of that device. See id. The final regulations also include a new example for advertising services. See § 1.250(b)–5(e)(5)(ii)(C) (*Example 3*).

Electronically supplied services are also different from other general services because the renderer will generally be able to determine where the service is accessed by using the recipient's IP address or through other means. The Treasury Department and the IRS have determined that the point of access serves as a reliable proxy for where the business recipient receives the benefit of the service. Therefore, the final regulations provide that with respect to electronically supplied services provided to a business recipient, the operations of the business recipient that benefit from the general service are deemed to be located where the general service is accessed. See § 1.250(b)–5(e)(2)(iii). The final regulations also provide that if the location where the business recipient accesses the electronically supplied service is unavailable (such as where the location of access cannot be reliably determined using the location of the IP address of the device used to receive the service), and the gross receipts from all services with respect to the business recipient (or any related party to the business recipient) are in the aggregate less than $50,000, the operations of the business recipient that benefit from the general service provided by the renderer are deemed to be located at the recipient's billing address. Id. The final regulations also include new examples for electronically supplied services. See § 1.250(b)–5(e)(5)(ii)(E) and (F) (*Example 5* and *6*).

d. Substantiating General Services Provided to Business Recipients

As discussed in part II of this Summary of Comments and Explanation of Revisions section, the final regulations replace the documentation requirements with new substantiation requirements for certain transactions, including general services provided to business recipients. The final regulations provide that a general service provided to a business recipient is a FDDEI service only if the taxpayer maintains sufficient substantiation to support its determination of the extent to which the service benefits a business recipient's operations outside the United States. See § 1.250(b)–5(e)(4). A taxpayer satisfies this requirement by either obtaining credible evidence establishing the extent to which operations of the business recipient benefit from the service or preparing a statement that supports its determination with corroborating evidence. See § 1.250(b)–5(e)(4). The final regulations explain that the determination of the portion of the service that will benefit the business recipient's operations located outside the United States may be based on evidence obtained from the business recipient, such as statements made by the recipient regarding the need for the service or data on the sales of the business recipient's operations, or the taxpayer's own records, such as time spent working with the business recipient's different offices. See § 1.250(b)–5(e)(4)(ii).

As explained in part VII.C.4 of this Summary of Comments and Explanation of Revisions section, the Treasury Department and the IRS have determined that it is unnecessary to delineate which specific methods satisfy substantiation. If the taxpayer substantiates its determination with evidence provided by the business recipient, the final regulations do not specify what information must be included in the statement beyond requiring that it must establish the extent to which the service benefits operations located outside the United States. See § 1.250(b)–5(e)(4)(i). The Treasury Department and the IRS understand that service recipients may not be willing to provide information about their business to taxpayers. Accordingly, the final regulations do not require the evidence to specify which of a business recipient's locations benefit from a service (for example, the business recipient's European operations rather than its Asian operations), just the portion of the service that benefits operations outside the United States generally.

C. Proximate Services

The proposed regulations provided that the provision of a proximate service to a recipient located outside the United States is a FDDEI service. See proposed § 1.250(b)–5(f). The proposed regulations defined a proximate service as a service, other than a property service or transportation service, substantially all of which is performed in the physical presence of the recipient or, in the case of a business recipient, its employees. See proposed § 1.250(b)–5(c)(6).

Comments requested that the final regulations expand the definition of a proximate service in proposed § 1.250(b)–5(c)(6) to include services performed in the physical presence of additional persons working for a business recipient, including that business's own employees, the employees of a related party of the recipient, or the recipient's contract workers or agents. In response to these comments, the final regulations expand the definition of a proximate service to provide that it means a service, other than a property service or a transportation service, provided to a recipient, but only if substantially all of the service is performed in the physical presence of the recipient or persons working for the recipient such as

employees, contractors, or agents. See § 1.250(b)–5(c)(8).

Comments also recommended that the final regulations provide that income received for the provision of proximate services, which must be performed outside the United States to qualify as a FDDEI service, is not treated as foreign branch income for purposes of section 250. The comments explained that taxpayers providing such services may potentially be deemed to operate a branch in the country in which the service occurs. The comments asserted that it is contrary to the purpose of section 250 for income from a FDDEI service (a proximate service provided outside the United States) to be excluded from FDDEI because the income is also foreign branch income. The comments made similar arguments with respect to property services, and one comment suggested that this concern applies to all services.

As explained in part IV.B of this Summary of Comments and Explanation of Revisions section, in response to comments, the final regulations confirm that there is one consistent definition of foreign branch income in both §§ 1.250(b)–1(c)(11) and 1.904–4(f)(2). The fact that the regulations under section 250 otherwise would treat certain income as eligible for FDII is irrelevant for purposes of determining whether the income is foreign branch income under section 904(d)(2)(J). Further, as acknowledged by the comments, providing a proximate service (or any other service) outside the United States does not necessarily create a foreign branch; therefore, not all income from proximate services performed outside the United States will be foreign branch income. Accordingly, the final regulations do not adopt these comments.

D. Property Services

The proposed regulations provided that a property service is a FDDEI service if it is provided with respect to tangible property located outside the United States, but only if the property is located outside the United States for the duration of the period the service is performed. See proposed § 1.250(b)–5(g).

1. Qualification of Property Services as FDDEI Services

Several comments recommended that the final regulations remove the mutually exclusive categories of services in proposed § 1.250(b)–5(b) because, according to the comments, they are inconsistent with section 250(b)(4)(B), which treats as FDDEI services those provided to any person, or with respect to property, not located within the United States. Comments asserted that the statute is disjunctive and requires that a service with respect to property gives rise to FDDEI if the service is provided to a person located outside the United States, regardless of the location of the serviced property.

The final regulations do not adopt these comments. Section 250(b)(4)(B) refers to persons and property disjunctively, which indicates that Congress intended for there to be a category of services provided with respect to persons located outside the United States that would be FDDEI services and a separate category of services provided with respect to property located outside the United States that would be FDDEI services. The proposed regulations gave effect to this intent. The statute and legislative history are ambiguous, however, as to whether Congress intended for *all* services provided with respect to persons located outside the United States and *all* services provided with respect to property located outside the United States to be included within the scope of the statute.

The Treasury Department and the IRS have determined that property services must be provided with respect to property located outside the United States in order to qualify as FDDEI services. The purpose of the section 250 deduction is to help neutralize the role that tax considerations play when a taxpayer chooses the location of intangible income attributable to foreign-market activity, that is, whether to earn such income through its U.S.-based operations or through its CFCs. See Senate Committee on the Budget, 115th Cong., ''Reconciliation Recommendations Pursuant to H. Con. Res. 71,'' at 375 (Comm. Print 2017). Providing a FDII deduction for all property services performed in the United States with respect to property with owners located outside the United States, regardless of the property's connection to foreign markets, would not further that purpose. Furthermore, even if the statute required that property services provided to any person located outside the United States could qualify as FDDEI services, the statute does not specify how to determine the location of such person. In the case of property services, the Treasury Department and the IRS have determined that basing the location of such person on the location of the property that the person owns is most consistent with the nature of a property service and the location of the benefit that is being provided. Therefore, even under the comment's alternative reading of section 250(b)(4)(B), the Treasury Department and the IRS have determined that property services should be limited to those services provided to property located outside the United States.

However, in recognition of the fact that some property services performed within the United States may nonetheless be connected to foreign markets, as discussed in part VIII.D.2 of this Summary of Comments and Explanation of Revisions section, the final regulations expand the circumstances under which property services may qualify as FDDEI services notwithstanding the fact that the services are performed in the United States.

Several comments suggested that the final regulations clarify that the property services rules apply only to services that the taxpayer provides with respect to completed property that is in use by the property's owner, and thus, that manufacturing-related services (such as toll manufacturing) are not property services, but rather general services. The comments suggested that if manufacturing services are treated as property services, manufacturing services performed in the United States will never give rise to FDDEI even if the sale of the same property to a foreign person for a foreign use would have been a FDDEI sale. In response to the comments, the final regulations specify that manufacturing services *are* property services but allow property services performed in the United States to qualify as FDDEI services under some circumstances. See § 1.250(b)–5(c)(7) and (g)(2). These changes are described in part VIII.D.2 of this Summary of Comments and Explanation of Revisions section. Taken together, these changes allow manufacturing services performed in the United States to be FDDEI services in some circumstances.

In addition, one comment suggested that the definition of ''property service'' should be modified to remove the condition that only tangible property can be the subject of a property service. The comment states that services can be provided with respect to intangible property located outside the United States, and notes that the statute does not distinguish between services provided with respect to tangible and intangible property. The final regulations do not adopt this recommendation. Intangible property cannot be ''located'' outside the United States given that intangible property, by definition, does not have physical properties. Accordingly, the Treasury Department and the IRS determined that the general services rules, which look to the location of the recipient, are a more

appropriate framework for analyzing these types of services.

2. Services Provided With Respect to Property Temporarily Located in the United States

The proposed regulations provided that a property service is a FDDEI service only if the tangible property with respect to which the service is performed is located outside the United States for the duration of the period of performance, but requested comments regarding the treatment of property that is located in the United States only temporarily.

Comments requested that the final regulations provide that a property service is still a FDDEI service in part (or in full) if the property enters the United States temporarily while the services are performed, and included various recommendations for a safe harbor, including treating a property service as a FDDEI service if the property is present in the United States for a particular period while the property is out of commercial service. Some comments also requested that the types of property services that are FDDEI services should be expanded to include toll manufacturing arrangements for foreign persons. The comments pointed out that section 250(b)(4)(B) does not specify when property must be located outside the United States. The comments suggested that a special rule for property temporarily in the United States would be consistent with Congress's objective in enacting section 250, which they assert was to incentivize taxpayers to serve the foreign market. In addition, one comment asserted that the proposed regulations penalize a seller for entering into a services arrangement (such as toll manufacturing) instead of a sales arrangement.

The final regulations generally adopt the comments. The Treasury Department and the IRS agree that in certain circumstances, treating property services as FDDEI services is appropriate even if the service is provided within the United States. Accordingly, the final regulations include an exception for property services performed with respect to property that is temporarily located in the United States and treats those services as being provided with respect to tangible property located outside the United States if several conditions are satisfied. See § 1.250(b)–5(g)(2). Those conditions are that the property must be temporarily located in the United States for the purpose of receiving the property service; after the completion of the service, the property will be primarily hangared, docked, stored, or used outside the United States; the property is not used to generate revenue in the United States at any point during the duration of the service; and the property is owned by a foreign person that resides or primarily operates outside the United States.

E. Transportation Services

The proposed regulations provided that the provision of a transportation service is a FDDEI service if both the origin and the destination of the service are outside the United States. See proposed § 1.250(b)–5(h). Where either the origin or destination (but not both) are outside the United States, then 50 percent of the transportation service is considered a FDDEI service. The proposed regulations defined a transportation service as a service to transport a person or property using aircraft, railroad rolling stock, vessel, motor vehicle, or any similar mode of transportation. See proposed § 1.250(b)–5(c)(7).

Comments requested that the final regulations include elections with respect to cross-border transportation services, including an election for taxpayers to choose either (i) the 50-percent FDDEI treatment provided in the proposed regulations, or (ii) a bifurcation method under which the FDDEI treatment of income from the service is based on actual time or mileage, or (iii) a predominant location method in which all of the income from the service is FDDEI if the taxpayer can demonstrate that more than 50-percent of the services were provided to a person or with respect to property outside the United States on a mileage basis. A comment also requested clarification on whether intermediate domestic stops can be disregarded for purposes of determining the origin and destination of a transportation service.

The final regulations retain the rule in the proposed regulations. See § 1.250(b)–5(h). The Treasury Department and the IRS have determined that the primary benefit of the service relates to servicing the origin or destination market. A 50/50 allocation rule thus provides a simpler and more administrable rule for reflecting the value of each market when the origin or destination is in the United States. In addition, the Treasury Department and the IRS have determined that an elective rule that allows different taxpayers to choose the rule most favorable to their business models would result in inconsistent treatment of similarly situated taxpayers and lead to whipsaw for the IRS. In addition, the rule in the proposed regulations is clear that only the locations of the origin and destination, and not intermediate stops, are relevant to the determination. Accordingly, the final regulations do not adopt these comments. However, the final regulations clarify that freight forwarding and similar services are included within the definition of ''transportation services.'' See § 1.250(b)–5(c)(9).

IX. Comments on and Revisions to Proposed § 1.250(b)–6—Related Party Transactions

In the case of a sale of general property or a provision of a general service to a related party, proposed § 1.250(b)–6 provided additional requirements that must be satisfied for the transaction to qualify as a FDDEI sale or FDDEI service. These requirements must be satisfied in addition to the general requirements that apply to such sales and services as provided in proposed §§ 1.250(b)–3 through 1.250(b)–5.

A. Related Party Sales

1. Amended Return Requirement

The proposed regulations provided two distinct rules for determining whether a sale of property to a related party (related party sale) is a FDDEI transaction. One rule applied when the related party *resells* the purchased property in an unrelated party transaction, either without modification or where the related party incorporates the purchased property as a component of property that is then resold in an unrelated transaction. See proposed § 1.250(b)–6(c)(1)(i). A different rule applied when the related party *uses* the property in an unrelated transaction, either in connection with the sale of altogether different property or to provide a service. See proposed § 1.250(b)–6(c)(1)(ii).

The rule for resales in proposed § 1.250(b)–6(c)(1)(i) required that an unrelated party transaction actually occur before the taxpayer can treat the original sale to the related party as a FDDEI transaction. If an unrelated party transaction has not occurred by the filing date of the return that includes the original sale (FDII filing date), the taxpayer cannot immediately treat the sale to the related party as a FDDEI transaction. Instead, in the subsequent year when the unrelated party transaction occurs, the taxpayer can file an amended return for the tax year of the original related party sale treating that sale as a FDDEI transaction and determine its modified FDII benefit accordingly, assuming the period of

limitations provided by section 6511 remains open when the unrelated party transaction occurs.

In contrast to the resale rule of proposed § 1.250(b)–6(c)(1)(i), where a related party uses the property in an unrelated party transaction (rather than resells that property), the taxpayer was permitted under proposed § 1.250(b)–6(c)(1)(ii) to treat that related party sale as a FDDEI transaction so long as the taxpayer reasonably expected, as of the FDII filing date, that one or more unrelated party transactions will occur with respect to the property sold to the related party and that more than 80 percent of the revenue earned by the foreign related party will be earned from such unrelated party transaction or transactions.

Several comments noted administrative difficulties with the amended return requirement for resale transactions in proposed § 1.250(b)–6(c)(1)(i). Many comments questioned the requirement of filing an amended return, arguing that it was administratively burdensome (for taxpayers, the IRS, and even state tax authorities) to file or process multiple amended returns. Some comments noted that because of long production or sales cycles, an unrelated party transaction will often not occur by the FDII filing date and might not occur until after the period of limitations under section 6511 has closed so taxpayers would no longer have the ability to treat the related party sale as a FDDEI transaction. Other comments observed that a taxpayer cannot always trace whether any particular sale to a related party leads to a particular unrelated party transaction given that taxpayers often sell products of a fungible nature or rely on accounting systems that track inventory flows broadly rather than specifically identifying transactions item by item. For such taxpayers, it would be impractical to require tracing, whether at the FDII filing date or any other time.

The preamble to the proposed regulations invited comments on the procedure for amending returns or suggestions for other alternatives for accounting for information relating to foreign use acquired only after the filing of a corporation's original return. In response, several comments suggested allowing taxpayers to treat the sale to a related party as a FDDEI transaction in the year the related party sale occurred and, if an unrelated party transaction did not in fact occur in a later year, the taxpayer could adjust its FDDEI in that later year to recapture the FDII benefit it should not have claimed. Other comments responded with a range of other alternatives to the amended return requirement such as an election to defer the FDII benefit until the tax year of the unrelated party transaction or a carryforward mechanism for the amount of the original FDII benefit to the later year when the unrelated party transaction occurs (which would be based on the FDII that would have been available in the year of the related party sale and could either take the form of a deduction or a credit in the year of the unrelated transaction).

Some comments pointed out the different treatment of related party sales and the related party use rules of proposed § 1.250(b)–6(c)(1)(ii). Under the related party use rules, a taxpayer could treat a sale to a related party as a FDDEI transaction so long as the taxpayer reasonably expected that an unrelated party transaction would later occur, which would alleviate the administrative burdens of the amended return requirement. Under this approach, a taxpayer need not wait until the subsequent unrelated party transaction actually occurred to claim a FDII benefit in the year of the original sale. One comment noted that because the U.S. parent controls the process and all the sellers are related, the taxpayers would generally be in a position to know what products would be sold to foreign unrelated buyers for foreign use. Comments suggested similar treatment for both related party sales and related party use.

Comments further provided suggestions for how a taxpayer could demonstrate it had a reasonable expectation as of the FDII filing date that an unrelated party transaction would occur. Several comments requested the ability to use market research such as inventory turnover, statistical sampling, economic modelling or other similar methods, with one comment suggesting that the fungible mass rule in proposed § 1.250(b)–4(d)(3)(iii) also be adopted in this context. One comment suggested that an unrelated party transaction exists whenever the product sold is specifically designed for a foreign market or can only be used outside of the United States. Another noted that in some cases the related party buyer is contractually obligated to sell products only to unrelated foreign parties. Comments also noted that past practice could inform the reasonable expectation of unrelated party transactions.

The Treasury Department and the IRS agree with the concerns expressed by the comments about the administrative burdens that the amended return requirement can cause for both taxpayers and tax administrators. Therefore, the final regulations modify the resale rule in proposed § 1.250(b)–6(c)(1)(i) to allow a taxpayer to treat a sale to a related party as a FDDEI transaction in the tax year of the related party sale provided that an unrelated party transaction has occurred or will occur in the ordinary course of business with respect to the property sold to the related party, whether the property is a completed product or a component of a different product. The unrelated party sale can occur at any time in the future so that taxpayers with long production or sales cycles are not unduly prevented from claiming FDII benefits based on the period of limitations for filing an amended return under section 6511. The condition that the unrelated party transaction must be in the ordinary course of business is intended to exclude situations in which the resale is tangential to the business of the taxpayer and related party (for example, if the taxpayer sells a machine to a related party for the related party's consumption, and the machine is later sold by the related party for scrap or recycling).

The final regulations also remove the requirement that the FDII filing date is determinative with respect to related party sales and use of property in an unrelated party transaction. Taxpayers that engage in related party transactions should generally be able to obtain information after the FDII filing date that will confirm whether a related party sale is in fact a FDDEI sale or service. A rule that depends on the FDII filing date would create uncertainty during examinations if the FDII filing date is inconsistent with actual post-FDII filing date transactions. Therefore, if in fact, an unrelated party transaction does not actually occur in a future year, the related party sale would not be a FDDEI sale. This could also apply to related party services where a substantially similar service that occurs in a future year should be taken into account. See part IX.B.1. of this Summary of Comments and Explanation of Revisions section.

The final regulations also include guidance on how a taxpayer can demonstrate that an unrelated party sale will later occur. Taxpayers can rely on contractual restrictions or historical practices indicating that the related party only sells products to unrelated foreign customers. Moreover, if the design of a product indicates that it is destined only for foreign customers, taxpayers can establish that an unrelated party sale will occur with respect to that product.

In light of the more flexible approach to demonstrate that an unrelated party

transaction will occur, the final regulations do not include a de minimis rule such as treating the entire fungible mass of sales as for a foreign use if a seller obtains documentation establishing that 90 percent or more of the fungible mass is for a foreign use (or conversely, no portion of the fungible mass is treated as for a foreign use if the seller does not obtain documentation establishing that 10 percent or more of the fungible mass is for a foreign use) as explained in part VII.C.4 of this Summary of Comments and Explanation of Revisions section.

2. Intermediate Sales to a U.S. Related Party Before Eventual Sale to an Unrelated Party

The proposed regulations provided that for purposes of determining whether a related party sale is for a foreign use, all foreign related parties of the seller are treated as if they were a single foreign related party. Proposed § 1.250(b)–6(c)(3). This rule gave effect to section 250(b)(5)(C)(i)(I) (providing that a sale to a foreign related party may be for a foreign use if the property is ultimately sold by ''a'' foreign party to a foreign unrelated party) and allowed a sale to a foreign related party to be a FDDEI sale even if the property is resold to one or more other foreign related parties before the sale to an unrelated foreign person.

One comment requested that the final regulations clarify how the related party resale rule operates when the foreign related party buyer purchases a semi-finished product from the U.S. parent (or another domestic related party), finishes that product, and resells it to the U.S. parent (or another domestic related party) for ultimate sale to an unrelated person for a foreign use. The comment requested that the related party sale rule should apply notwithstanding the intermediate sale so long as the taxpayer can substantiate the ultimate sale of property to the unrelated foreign party. The comment argued that such a clarification would eliminate unwarranted disparate treatment for U.S. companies that engage in multiple related-party sales as compared to those that engage in just one step.

The Treasury Department and the IRS generally agree with this comment and have modified § 1.250(b)–6(c)(3) to provide that a U.S. person (either the seller itself or another U.S. person that is a related party of the seller) is treated as part of a single foreign related party. This rule only applies for purposes of determining whether the related party sale is for a foreign use; it does not modify or eliminate the requirement that a seller must sell property to a foreign person for the sale to be a FDDEI sale. However, the Treasury Department and the IRS are concerned that U.S. persons that are members of the same modified affiliated group, but not members of a consolidated group, could use this rule to avoid the requirement that a sale be made to a foreign person by inserting a foreign person, such as a foreign partnership, as an intermediary in the sale from one U.S. person to another U.S. person. The Treasury Department and the IRS have determined that it would be inappropriate to use the related party sales rules to expand the types of sales that are eligible to be treated as FDDEI sales in this way. Therefore, the rule does not treat a U.S. person as related to the seller if the U.S. person is not related to the seller under the 80 percent or more standard for vote or value in section 1504(a). See § 1.250(b)–6(c)(3).

3. Rule for Use of Property in an Unrelated Party Transaction

For transactions other than the resale of purchased property, such as where the foreign related party uses the purchased property to produce other property that is sold in unrelated party transactions, or where the foreign related party uses the property in the provision of a service in an unrelated party transaction, the proposed regulations provided that the sale of property does not qualify as a FDDEI sale unless, as of the FDII filing date, the seller reasonably expects that more than 80 percent of the revenue earned by the foreign related party from the use of the property in all transactions will be earned from unrelated party transactions that are FDDEI transactions (determined without regard to the documentation requirements in § 1.250(b)–4 or § 1.250(b)–5). See proposed § 1.250(b)–6(c)(1)(ii). One comment expressed concern with the 80 percent rule of the proposed regulations creating a cliff effect whereby a taxpayer would derive no FDII benefit if its revenues fell below this threshold. That comment suggested either lowering the threshold or replacing it with a sliding scale upon a certain minimum level of revenues. It also noted that it is unclear how revenue should be measured for purposes of this 80 percent rule, such as whether it should be based on the price of all sales to end user customers and whether it should just include sales to unrelated customers or also related party sales.

The Treasury Department and the IRS agree with the comment that the related party sale and related party use rules should have similar standards. To make this rule consistent with the standard in § 1.250(b)–6(c)(1)(i), the final regulations modify the rule to require that one or more unrelated party transactions occurs with respect to the property. The Treasury Department and the IRS expect that taxpayers have sufficient control over the supply chain involving controlled transactions to make this determination. In addition, to eliminate the potential cliff effect described in the comment, the final regulations remove the 80 percent rule and instead require the seller in the related party transaction to allocate the buyer's revenues ratably between related and unrelated party transactions based on revenues reasonably expected to be earned as of the FDII filing date. The final regulations also adopt the suggested clarification that revenue should be measured for this purpose based on the price of all transactions with unrelated parties.

Other comments requested clarifications and relevant examples concerning the definition of a component under proposed § 1.250(b)–6(b)(5)(ii) and how a component can be distinguished from a sale of property for use in connection with property sold to an unrelated party under proposed § 1.250(b)–6(b)(5)(iii). Several comments noted that the preamble to the proposed regulations stated that the component rule of proposed § 1.250(b)–4(d)(2)(iii)(C) did not apply for purposes of determining what is a component for purposes of proposed § 1.250(b)–6(b)(5)(ii) and requested that this clarification be included in the text of the final regulations. In response to the comments, the final regulations remove the reference to ''component'' in § 1.250(b)–6(b)(5)(ii) and replace it with ''constituent part'' to avoid any implication that the component rule of § 1.250(b)–4(d)(1)(iii)(C) may apply. Further, the final regulations modify the rule for a related party use transaction in § 1.250(b)–6(b)(3)(iii) to clarify that it does not include transactions in which the purchased property is a constituent part of the product sold, to eliminate any potential overlap with § 1.250(b)–6(b)(5)(ii). Lastly, the final regulations modify the example in § 1.250(b)–6(c)(4) to clarify that property that is used in connection with a sale to an unrelated party means property that is not a constituent part of the product that is ultimately sold.

B. Related Party Services

1. In General

The proposed regulations generally provided that a provision of a general service to a business recipient that is a

related party qualifies as a FDDEI service only if the service is not substantially similar to a service provided by the related party to persons located within the United States. See proposed § 1.250(b)–6(d)(1). One comment noted that, unlike the related party sales rule, the related party services rules of proposed § 1.250(b)–6(d) did not specify whether the substantially similar service needs to be provided before the FDII filing date for the rule to apply. The comment recommended a rule that is consistent with the related party sales rules. It suggested that the final regulations provide that the service to the related party is treated as a FDDEI transaction in the year provided to the related party if the substantially similar service test was not implicated in that year, but that taxpayers should be required to amend that return to reverse the FDII benefit if a substantially similar service occurs in a later year.

As discussed in part IX.A.1. of this Summary of Comments and Explanation of Revisions section, the final regulations eliminate the amended return requirement for related party sales and allow such sales to be FDDEI sales as long as an unrelated party transaction will occur. Accordingly, the final regulations do not adopt the suggestion to treat a service as not being subject to the substantially similar service test as long as there is no substantially similar service in the year of the related party transaction. However, the Treasury Department and the IRS agree with the recommendation that the related party sales and services rules should be made consistent with respect to the timing element of the unrelated transaction. Therefore, the final regulations provide that a related party service is a FDDEI service only if the related party service is not substantially similar to a service that has been or will be provided by the related party to a person located within the United States. The fact that a substantially similar service will occur in a future year does not prevent that substantially similar service from being considered in the determination of whether a related party service is a FDDEI service.

2. Clarifications Related to Benefit and Price Tests

Under the proposed regulations, a service provided by a renderer to a related party is ''substantially similar'' to a service provided by the related party to a person located within the United States if the renderer's service (or ''related party service'') is used by the related party to provide a service to a person located within the United States and either the ''benefit test'' of proposed § 1.250(b)–6(d)(2)(i) or the ''price test'' of proposed § 1.250(b)–6(d)(2)(ii) is satisfied. The benefit test is satisfied if 60 percent or more of the benefits conferred by the related party service are to persons located within the United States. See proposed § 1.250(b)–6(d)(2)(i). Under the price test, a service provided by a renderer to a related party is ''substantially similar'' to a service provided by the related party to a person located within the United States if the renderer's service is used by the related party to provide a service to a person located within the United States and 60 percent or more of the price that persons located within the United States pay for the service provided by the related party is attributable to the renderer's service. See proposed § 1.250(b)–6(d)(2)(ii).

One comment supported these bright line tests for substantially similar services as practicable but asserted it would be burdensome for taxpayers to have to apply both tests, and therefore requested that the final regulations only retain the price test, or alternatively should apply the tests conjunctively so that only if both tests are met is a service considered substantially similar to a service provided by a related party to a person in the United States.

The Treasury Department and the IRS have determined that these two tests consider distinct factors, both of which are relevant, and therefore the final regulations do not adopt the suggestion that the benefit test be eliminated or that the tests be made conjunctive. Both tests address concerns with ''round tripping'' arrangements where the provision of services primarily benefits persons within the United States, but a related party located outside the United States is interposed in order to qualify the initial transaction as a FDDEI transaction. While the two tests may overlap, they also serve different purposes and address different concerns. One example that implicates the benefit test is when a related party bundles its own services that provide minimal benefit to persons located outside the United States with other services that primarily benefit persons located within the United States. The price test addresses situations such as when a taxpayer provides a broad range of services to a related party located outside the United States but one component of the service is provided unchanged to persons located within the United States and this is reflected in the price charged to the U.S. customer compared to the price charged to the related party. Consequently, in the absence of the price test, a related party service that satisfies the benefit test could qualify as a FDDEI transaction even if the related party service accounts for 60 percent or more of the total price charged to customers located within the United States. However, the final regulations clarify that the benefit test is met only if 60 percent or more of the benefits conferred by the related party service are directly used by the related party to confer benefits on consumers or business recipients within the United States. See § 1.250(b)–6(d)(2)(i). For example, if a business recipient located in the United States hires the related party to provide a consulting service, and the related party hires the taxpayer to perform research that is used by the related party in performing the consulting service, the related party will have directly used the taxpayer's research in performing the consulting service for the business recipient located within the United States. Services provided to the related party that will only indirectly benefit the related party's service recipients (generally, when the related party's service recipients would not be willing to pay for the related party service) are not ''substantially similar'' to the services provided by the related party. See § 1.482–9(l)(3)(ii) for an explanation of indirect or remote benefits.

Proposed § 1.250(b)–6(d)(3) provided that for purposes of applying the price and benefit tests, the location of a consumer or business recipient with respect to a related party service is determined under the principles that apply to FDDEI services. One comment requested the addition of a clarifying sentence to proposed § 1.250(b)–6(d)(3) indicating that the benefits conferred and price paid for the related party service that is provided to persons located in the United States must be allocated based on the locations of the business recipients that benefit from these services provided by the related party. In response to this comment, the final regulations clarify that if the related party provides a service to a business recipient, the business recipient is treated as a person located within the United States to the extent that the service confers a benefit on the business recipient's operations located within the United States. The price paid to the related party is allocated proportionally based on the locations of the business recipient that benefit from the services provided by the related party. See § 1.250(b)–6(d)(3)(i). The final regulations also clarify that for purposes of applying the price test, if the benefits conferred by the related party service

are to persons located in the United States and outside the United States, the price paid by the related party for the related party service is allocated proportionally based on the locations of the business recipient that benefit from the services provided by the related party. See § 1.250(b)–6(d)(3)(ii). In addition, the examples have been revised to clarify the application of the rules. See § 1.250(b)–6(d)(4).

X. Comments on and Revisions to Proposed § 1.962–1

Proposed § 1.962–1(b)(1)(i) allowed individuals making an election under section 962 to take into account the deduction for GILTI under section 250. Specifically, proposed § 1.962–1(b)(1)(i)(A)(*2*) provided that ''taxable income'' for purposes of section 962 includes GILTI inclusions, and proposed § 1.962–1(b)(1)(i)(B)(*3*) specified that the section 250 deduction for GILTI is permitted as a deduction to arrive at ''taxable income.'' The final regulations retain these rules without change.

One comment noted that the reference to section 960(a)(1) in § 1.962–1(b)(2) was obsolete after the revisions to section 960 made by the Act, and that the regulations lacked any reference to foreign tax credits with respect to GILTI inclusions. The Treasury Department and the IRS agree with this comment. Accordingly, § 1.962–1(a)(2), (b)(2), and (c) have been updated to replace obsolete cross-references to section 960(a)(1) with cross-references to section 960(a); § 1.962–1(b)(2) has been updated to clarify that foreign tax credits with respect to GILTI inclusions under section 960(d) are available to individuals making section 962 elections (subject to the limitations of section 904(c) and 904(d)(1)(A)); and § 1.962–1(c) has been updated to provide a revised example illustrating the application of § 1.962–1. The limitation on the section 11(c) surtax exemption (repealed in 1978 [7]) provided in § 1.962–1(b)(1)(ii) has also been struck from § 1.962–1.

Finally, the Treasury Department and the IRS understand that there is uncertainty regarding the situations in which individuals may make a section 962 election on an amended return. The Treasury Department and the IRS are considering issuing further guidance under section 962. Until further guidance on this issue is published, individuals may make an otherwise valid section 962 election on an amended return for the 2018 tax year and subsequent years, regardless of circumstance, provided the interests of the government are not prejudiced by the delay, as described in § 301.9100–3(c). For example, the interests of the government could be prejudiced when a section 962 election is made on an amended return resulting in an overpayment in a year for which the period to file a claim for refund is open under section 6511 and simultaneously increasing the amount of U.S. tax due in years for which the assessment period under section 6501 has expired.

XI. Comments on and Revisions to Proposed §§ 1.1502–12, 1.1502–13, and 1.1502–50—Consolidated Section 250

Proposed § 1.1502–50 provided that the section 250 deduction of a member of a consolidated group (member) is determined by reference to the relevant items of all members of the same consolidated group (single-entity treatment). Single-entity treatment ensures that the aggregate amount of section 250 deductions allowed to members appropriately reflects the income, expenses, gains, losses, and property of the consolidated group as a whole. To effectuate single-entity treatment, proposed § 1.1502–50 aggregated the DEI, FDDEI, DTIR, and GILTI of all members, the amounts of which are used to calculate an overall deduction amount for the consolidated group. See proposed § 1.1502–50(e) (providing definitions). The aggregate deduction amount for the consolidated group is then allocated among the members on the basis of their respective contributions to consolidated FDDEI and consolidated GILTI. See proposed § 1.1502–50(b).

A. Single-Entity Treatment

Two comments addressed the computation of a member's section 250 deduction. The comments generally supported single-entity treatment. However, one comment recommended permitting a taxpayer to elect out of single-entity treatment with respect to the section 250 deduction attributable to GILTI. The comment expressed concern about applying the taxable income limitation in section 250(a)(2) to companies with pre-Act NOLs while also arguing that the NOLs of a consolidated group should not affect the section 250 deduction attributable to GILTI of a member that has not contributed to the NOLs. The Treasury Department and the IRS decline to adopt this recommendation because single-entity treatment ensures that a consolidated group's income tax liability is clearly reflected, as required by section 1502. Permitting taxpayers to elect out of single-entity treatment would incentivize inappropriate planning with respect to the location of CFCs within the consolidated group and undermine the policy behind the enactment of section 250.

B. Life-Nonlife Consolidated Groups

The second comment raised concerns that the proposed regulations may be incompatible with the rules and framework of § 1.1502–47 for life-nonlife consolidated groups. The comment asserted that single-entity treatment could result in an inappropriate permanent disallowance of the section 250 deduction in a life-nonlife consolidated group if the allocation of the section 250 deduction among members is made on a subgroup basis. The comment recommended applying the section 250 deduction based on the life-nonlife consolidated group's consolidated taxable income, rather than taking the deduction into account at the subgroup-level. Under the comment's recommended approach, the section 250 deduction would be treated as a consolidated deduction to determine whether it can be used against consolidated taxable income before being allocated to a member. The Treasury Department and the IRS are studying these concerns and request comments on this topic.

C. Qualified Business Asset Investment

Proposed § 1.1502–50(c)(1) provided that, for purposes of determining a member's QBAI, the basis of specified tangible property does not include an amount equal to any gain or loss realized with respect to such property by another member in an intercompany transaction, whether or not such gain or loss is deferred. This rule was intended to negate the impact (whether positive or negative) of an intercompany sale of property on the computation of DII, in accordance with single-entity treatment. However, in most relevant cases, once an intercompany item has been included in income, there are real, external consequences to the group. For example, if gain has been included in consolidated taxable income (and in the tax system), the group should take the associated increase in tax basis into account. Therefore, these final regulations limit the application of the rule negating the impact of intercompany sales of property to the period during which the intercompany gain or loss remains deferred under § 1.1502–13. See § 1.1502–50(c)(1)(i).

The Treasury Department and the IRS are also concerned that single-entity treatment is not achieved in certain intercompany transactions involving the transfer of a partnership interest if such

[7] Public Law 95–600, 92 Stat. 2763 (1978).

transfers result in an increase or decrease in the basis of specified tangible property under section 743(b) and thus impact the computation of DII. The final regulations therefore provide that a member's partner-specific QBAI basis includes a basis adjustment under section 743(b) resulting from an intercompany transaction only when, and to the extent, gain or loss, if any, is recognized in the transaction and no longer deferred under § 1.1502–13. See § 1.1502–50(c)(1)(ii).

XII. Applicability Dates

As proposed, proposed §§ 1.250(a)–1 through 1.250(b)–6 would apply to taxable years ending on or after March 4, 2019. However, the proposed regulations also provided that, for taxable years beginning on or before March 4, 2019, taxpayers may use any reasonable documentation maintained in the ordinary course of the taxpayer's business that establishes that a recipient is a foreign person, property is for a foreign use (within the meaning of proposed § 1.250(b)–4(d) and (e)), or a recipient of a general service is located outside the United States (within the meaning of proposed § 1.250(b)–5(d)(2) and (e)(2)), as applicable, in lieu of the documentation required in proposed §§ 1.250(b)–4(c)(2), (d)(3), and (e)(3) and 1.250(b)–5(d)(3) and (e)(3), provided that such documentation meets the reliability requirements described in proposed § 1.250(b)–3(d). The proposed regulations also provided that taxpayers may rely on proposed §§ 1.250(a)–1 through 1.250(b)–6 for taxable years ending before March 4, 2019.

The final regulations modify the applicability dates in proposed §§ 1.250(a)–1 through 1.250(b)–6 as follows. Except for § 1.250(b)–2(h), the rules in §§ 1.250(a)–1 through 1.250(b)–6 apply to taxable years beginning on or after January 1, 2021. Section 1.250(b)–2(h), which contains an anti-abuse rule for certain transfers of property, applies to taxable years ending on or after March 4, 2019, consistent with the applicability date in the proposed regulations. See, however, part V.C of this Summary of Comments and Explanation of Revisions section for a transition rule relating to transfers that occur before March 4, 2019.

However, taxpayers may choose to apply the final regulations to taxable years beginning before January 1, 2021, provided that they apply the final regulations in their entirety (other than the special substantiation requirements in § 1.250(b)–3(f) and the applicable provisions in § 1.250(b)–4(d)(3) or § 1.250(b)–5(e)(4)). See section 7805(b)(7). Taxpayers will be required to substantiate under section 6001 that any sale or service qualifies for a section 250 deduction. Alternatively, taxpayers may rely on proposed §§ 1.250(a)–1 through 1.250(b)–6 in their entirety for taxable years beginning before January 1, 2021, except that taxpayers relying on the proposed regulations may rely on the transition rule for documentation for all taxable years beginning before January 1, 2021 (rather than only for taxable years beginning on or before March 4, 2019). See also part II of this Summary of Comments and Explanation of Revisions section.

Section 1.962–1(b)(1)(i)(B)(*3*), which allows individuals making an election under section 962 to take into account the section 250 deduction, applies to taxable years of a foreign corporation ending on or after March 4, 2019, and with respect to a U.S. person, for the taxable year in which or with which such taxable year of the foreign corporation ends.

Proposed § 1.962–1(b)(1)(i)(A)(*2*), which updated the regulations to conform to the enactment of section 951A by providing that ''taxable income'' for purposes of section 962 includes GILTI inclusions, is proposed to apply beginning with the last taxable year of a foreign corporation beginning before January 1, 2018, and with respect to a U.S. person, for the taxable year in which or with which such taxable year of the foreign corporation ends. The final regulations provide that § 1.962–1(b)(1)(i)(A)(*2*) applies to taxable years of a foreign corporation ending on or after March 4, 2019, and with respect to a U.S. person, for the taxable year in which or with which such taxable year of the foreign corporation ends. Under section 951A(f)(1)(A), GILTI inclusions are treated in the same manner as amounts included under section 951(a)(1)(A) for purposes of section 962. Accordingly, individuals making an election under section 962 were required to include GILTI in ''taxable income'' for purposes of section 962 irrespective of this update to the regulations.

Section 1.962–1(a)(2), (b)(1)(ii), (b)(2)(i) through (iii), and (c), which update obsolete cross-references to former section 960(a)(1), strike the section 11(c) surtax exemption limitation, update rules on the allowance of foreign tax credits to individuals making an election under section 962 (including with respect to the carryback and carryover of such credits), and provide an updated example illustrating the application of § 1.962–1, apply to taxable years of a foreign corporation ending on or after July 15, 2020, and with respect to a U.S. person, for the taxable year in which or with which such taxable year of the foreign corporation ends. With respect to foreign tax credits, section 960(d) provides domestic corporations (which includes individuals making an election under section 962) a credit for taxes attributable to tested income, and section 904(c) and 904(d)(1)(A) prohibit taxpayers from carrying back or carrying over any excess foreign taxes attributable to tested income as a credit in their first preceding taxable years and in any of their first 10 succeeding taxable years. Accordingly, individuals making an election under section 962 that claimed foreign tax credits attributable to tested income were subject to the limitations of sections 960(d), 904(c), and 904(d)(1)(A) irrespective of the updates to the regulations.

One comment requested clarification that proposed § 1.962–1 can be applied for taxable years beginning in 2018. With respect to taxable years before the relevant final regulations are applicable, the final regulations provide that taxpayers may choose to apply the provisions of § 1.962–1(a)(2), (b)(1)(i)(A)(*2*), (b)(1)(i)(B)(*3*), (b)(1)(ii), (b)(2)(i) through (iii), and (c) for taxable years of a foreign corporation beginning on or after January 1, 2018, and with respect to a U.S. person, for the taxable year in which or with which such taxable year of the foreign corporation ends.

Proposed § 1.1502–50 was proposed to apply to consolidated return years ending on or after July 15, 2020. The final regulations provide that § 1.1502–50 applies to consolidated return years beginning on or after January 1, 2021. Taxpayers that choose to apply the final regulations under §§ 1.250(a)–1 through 1.250(b)–6 to taxable years beginning before January 1, 2021, must also apply the provisions in § 1.1502–50 to such years. Similarly, taxpayers that rely on proposed §§ 1.250(a)–1 through 1.250(b)–6 for taxable years beginning before January 1, 2021, must also follow proposed § 1.1502–50.

Proposed §§ 1.6038–2(f)(15) and 1.6038A–2(b)(5)(iv) are proposed to apply with respect to information for annual accounting periods beginning on or after March 4, 2019. See sections 6038(a)(3) and 7805(b)(1)(B). Proposed § 1.6038–3(g)(4) is proposed to apply to taxable years of a foreign partnership beginning on or after March 4, 2019. See section 7805(b)(1)(B). No changes were made to the proposed applicability date in the final regulations.

XIII. Comment Regarding Special Analyses

One comment asserted that in issuing the proposed regulations, the Treasury Department and the IRS did not comply with Executive Orders 12866 and 13563 because the costs and benefits analysis required under the executive orders did not quantify the burden imposed by the documentation requirements for larger business entities that were ineligible for the small business and small transaction exceptions.

The Treasury Department and the IRS complied with the applicable requirements under Executive Orders 12866 and 13563 when issuing the proposed regulations. See 84 FR 8188, Special Analyses section. In addition, an economic analysis of the impact of the substantiation requirements of the final regulations is contained in part I.C.1.a.i of the Special Analyses section. As required by the Regulatory Flexibility Act, an analysis of the impact of the final regulations on small businesses is contained in part III of the Special Analyses section.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Orders 13771, 13563, and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. For purposes of Executive Order 13771, this final rule is regulatory.

These final regulations have been designated as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget (OMB) regarding review of tax regulations. The Office of Information and Regulatory Affairs (OIRA) has designated the final rulemaking as significant under section 1(c) of the Memorandum of Agreement. Accordingly, OMB has reviewed the final regulations.

A. Background

The Tax Cuts and Jobs Act (the ''Act'') introduced new section 250 of the Internal Revenue Code, which provides a deduction for (1) a portion of profits attributable to U.S. activities that serve foreign markets and (2) a portion of profits of controlled foreign corporations (''CFCs''). The deduction has the effect of reducing the role that U.S. tax considerations play in a domestic corporation's decision about whether to service foreign markets directly or through a CFC, and also of protecting the U.S. tax base against base erosion incentives created by the new participation exemption system established under section 245A.[8]

At the most basic level, the section 250 deduction is available to domestic corporations with respect to their ''excess return'' (that is, their return in excess of a fixed return on tangible assets) derived from serving foreign markets. This deduction results in a lower effective rate of U.S. tax on the corporations' foreign-derived intangible income (''FDII'') and global intangible low-taxed income (''GILTI''). FDII is the portion of the ''excess return'' derived from serving foreign markets directly from the United States, while GILTI is the portion of the ''excess return'' derived through foreign affiliates. FDII and GILTI are calculated based on formulas set out in sections 250 and 951A, respectively. For taxable years between 2018 and 2025, section 250 generally allows a deduction equal to the sum of 37.5 percent of the corporation's FDII plus 50 percent of its GILTI (thereafter, these deductions are reduced to 21.875 percent and 37.5 percent, respectively). These deduction rates are intended to produce comparable tax rates on income earned from serving foreign markets, regardless of whether such income is earned directly by a domestic corporation or by its CFCs.[9]

On March 6, 2019, the Treasury Department and the IRS published proposed regulations relating to section 250 (''proposed regulations'').

B. Need for Final Regulations

Regulations are needed to aid taxpayers in determining the amount of their section 250 deduction. The final regulations are also needed to respond to comments received on the proposed regulations.

C. Baseline

The economic analysis that follows compares the final regulations to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of the final regulations. This no-action baseline reflects the current environment including the existing international tax regulations pursuant to the Act, prior to any amendment by the final regulations.

D. Economic Analysis

The final regulations provide certainty and clarity to taxpayers regarding the section 250 deduction. In the absence of such guidance, the chance that different taxpayers would interpret the statute differently would be exacerbated. Similarly situated taxpayers might interpret the statutory rules pertaining to the treatment of particular sales or services differently, with one taxpayer pursuing a sale that another taxpayer might decline to make because of different interpretations of how the income would be treated under section 250. If this second taxpayer's activity were more profitable, an economic loss is generated. Such situations are more likely to arise in the absence of guidance. While no guidance can curtail all differential or inaccurate interpretations of the statute, the final regulations significantly mitigate the chance for differential or inaccurate interpretations and thereby increase economic efficiency.

The Treasury Department and the IRS expect that in the absence of this guidance taxpayers would undertake fewer eligible sales and services. Thus, the final regulations will generally enhance sales and services across certain eligible activities relative to the no-action baseline. Because of the scale of U.S. economic activity generally associated with foreign use (independent of any specific definition of foreign use) and because of the general responsiveness of economic activity to effective tax rates, which may be affected by the section 250 deduction, we project that the final regulations will have annual economic effects greater than $100 million (2020 dollars) relative to the no-action baseline.

The Treasury Department and the IRS have not made quantitative estimates of the effects of these final regulations on the volume of eligible sales and services or on the overall size or composition of U.S. economic activity relative to the no-action baseline or regulatory alternatives. The Treasury Department and the IRS have not undertaken these estimates because we do not have sufficiently detailed data or models for: (i) The costs to taxpayers of establishing that particular transactions are eligible for the section 250 deduction

[8] See Senate Explanation, at 370 (''[O]ffering similar . . . rates for intangible income derived from markets, whether through U.S.-based operations or through CFCs, reduces or eliminates the tax incentive to locate or move intangible income abroad, thereby limiting one margin where the Code distorts business investment decisions.'').

[9] See Joint Comm. on Taxation, General Explanation of Public Law 115–97, at 377–383.

(''substantiation requirements'') under various standards of substantiation; (ii) the effect of differences in substantiation requirements on economic activity, including both activities that are eligible for the section 250 deduction and activities not eligible for the section 250 deduction under the final regulations versus regulatory alternatives; and (iii) the economic effects of other clarifications in the final regulations, including the treatment of military sales, relative to the no-action baseline and regulatory alternatives. Each of these items would be needed to provide sufficiently precise estimates of the effects of these final regulations.

The Treasury Department and the IRS project that as many as 350,000 taxpayers may be potentially affected by the final regulations. This estimate is based on International Trade Administration (''ITA'') statistics of the number of companies engaged in export activities.[10] No data derived from tax forms were available to provide an estimate of potentially affected taxpayers because the section 250 deduction is new and the transactions that would now give rise to a section 250 deduction were not previously separately reported on tax forms. No comments were received on estimates of the number of affected taxpayers provided in the proposed regulations. The Treasury Department and the IRS plan to include estimates of the number of affected taxpayers in analysis of any future regulatory guidance when possible.

The economic effects of major provisions of these final regulations are discussed qualitatively in Part I.C and are separately categorized depending on whether the provisions have been significantly revised from the proposed regulations or are largely unchanged from the proposed regulations.

The Treasury Department and the IRS solicit comments on the economic effects of the regulations.

1. Economic Effects of Provisions Substantially Revised From the 2019 Section 250 Proposed Regulations

a. Documentation Requirements

The statute provides a section 250 deduction for certain income derived by the taxpayer from serving foreign markets but it does not provide detail regarding what it means to ''serve foreign markets'' or how to document that fact. Many of the calculations needed for the section 250 deduction are based on Foreign Derived Deduction Eligible Income (FDDEI), which is certain income derived from sales of property to foreign persons for ''foreign use'' and from the provision of services to persons, or with respect to property, located outside the United States. The statute is likewise silent on the meaning of ''foreign use.''

The proposed regulations defined terms and prescribed specific documents that taxpayers were required to hold to establish that such income was derived from serving foreign markets. Comments to the proposed regulations, however, noted that the documentation requirements were prohibitively burdensome because, contrary to the original understanding of the Treasury Department and the IRS, taxpayers frequently do not have ready access to those types of documentation. Therefore, comments argued, the proposed regulations frequently created compliance costs that were high relative to the value of the deduction. In addition, comments explained that for taxpayers that enter into long term contracts, it was difficult to simultaneously satisfy the proposed regulations' requirements that the documentation be obtained by the FDII filing date and also that it be obtained no earlier than one year before the date of the sale or the service. Commenters also noted that the Regulatory Flexibility Act analysis for the proposed regulations provide an estimate of the compliance burden for small entities but did not provide a comparable estimate for larger entities, which could have had a considerably higher burden.

Because of these difficulties, the Treasury Department and the IRS adopt a different approach in the final regulations for the substantiation of foreign use for purposes of the section 250 deduction. This approach is described in sections 3.a.i–3.a.iii. For each of the items in 3.a.i–3.a.iii, the approach in the final regulations is significantly more flexible than the specific documentation requirements in the proposed regulations.

The Treasury Department and the IRS have determined that the substantiation requirements in the final regulations provide a reasonable balance of compliance costs and the administrative burden of ensuring that the transactions are consistent with the intent and purpose of the statute.

i. General Substantiation Versus Specific Substantiation

The statute generally provides a section 250 deduction for income that is for foreign use and specifies that the Secretary should issue regulations to specify how foreign use should be substantiated for purposes of tax administration. To address the substantiation issue, the Treasury Department and the IRS considered: (i) Which types of transactions should be subject (only) to the general substantiation rules that apply to all deductions, versus requiring specific substantiation, and (ii) for those transactions for which more specific substantiation will be required, what forms specific substantiation should take.

The final regulations specify that for many types of sales and services, eligibility for the section 250 deduction is subject only to the general requirement under the Code that eligibility for deductions must be supported by sufficient substantiation, including through the use of available business records. The final regulations provide substantiation requirements that are generally similar to the substantiation requirements for other types of deductions, which helps standardize deduction-related benefits in the Code and thereby minimizes the risk of unintended complications across provisions of the Code.

The Treasury Department and the IRS considered allowing general substantiation for all types of transactions. However, the Treasury Department and the IRS determined that certain types of transactions pose a higher risk of being treated as eligible transactions (FDDEI transactions) without the taxpayer having generated revenue from serving foreign markets. For these certain transactions, the final regulations provide specific substantiation requirements. These requirements involve either (i) a specific document, (ii) information from the recipient obtained or created in the ordinary course of business, or (iii) a taxpayer statement with corroborating evidence (where the taxpayer chooses the form of corroborating evidence). In general, these requirements are substantially more flexible than the documentation requirements set forth in the proposed regulations because they allow taxpayers to choose the method of substantiation among a set of options and because this set includes options that are less onerous than in the proposed regulations. In addition, to further reduce compliance burdens relative to the proposed regulations, and in response to comments, the final regulations remove the requirement in the proposed regulations that the substantiating documents must be obtained no earlier than one year before the date of the sale or service.

The main categories of transactions for which specific substantiation is

[10] ITA data was accessed at *http://tse.export.gov/EDB/SelectReports.aspx?DATA=ExporterDB* in December, 2018.

required are: (i) Sales of intangible property; (ii) sales of general property to resellers and manufacturers; and (iii) the provision of general services to business recipients. These types of transactions generally have a higher potential for mischaracterization than other transactions for which general substantiation is required; for example, intangible property is often used both within and without of the United States, and without some specific substantiation documenting its use, the foreign portion could easily be overstated. Similarly, if a U.S. person sells a finished good to a foreign reseller, the final regulations require the taxpayer to provide evidence that the reseller will not immediately sell the property back into the United States; otherwise, the taxpayer could claim the section 250 deduction for what is effectively a sale for domestic use. The Treasury Department and the IRS have determined that this latter activity would not be consistent with the intent and purpose of the statute. In addition, in the case of general services (such as consulting or accounting services) provided to a business recipient that is an integrated multinational company with operations within and outside the United States, without substantiation the IRS would have difficulty verifying the extent to which the business recipient's operations outside the United States benefited from the service. Thus, the Treasury final regulations impose more thorough substantiation requirements for such types of transactions.

The specific substantiation requirements provide that a taxpayer may substantiate that a sale of general property to a distributor is for a foreign use by maintaining proof that property is specifically designed, labeled, or adapted for a foreign market or proof that the cost of shipping the property back to the United States relative to the value of the property makes it impractical that the property will be resold in the United States. Furthermore, in recognition of the fact that some taxpayers may not be able to substantiate their deductions with information already available to them, the specific substantiation requirements do not apply to taxpayer years beginning before January 1, 2021. In addition, the specific substantiation requirements do not apply to businesses with less than $25 million in gross receipts.

The Treasury Department and the IRS do not have readily available data or models to provide sufficiently precise estimates of the difference in compliance costs for these provisions between the final regulations and regulatory alternatives such as the proposed regulations.

ii. Removal of Specific References to Market Research

The proposed regulations contained specific rules regarding appropriate methods of documenting foreign use for: (i) Fungible mass property and (ii) general services provided to a business recipient located outside the United States. In particular, the proposed regulations provided that a seller could establish certain foreign use through market research, including statistical sampling, economic modeling and other similar methods. In light of the more flexible and less prescriptive approach to documentation generally taken by the final regulations relative to the proposed regulations, the Treasury Department and the IRS have determined that prescribing specific methods (such as market research) for determining the use of these types of property is not necessary and have further determined that general market research based on secondary sources could be misleading in this circumstance.

The Treasury Department and the IRS do not have readily available data or models to provide sufficiently precise estimates of the difference in compliance costs for these items between the final regulations and regulatory alternatives such as the proposed regulations.

iii. Digital Content, Electronically Supplied Services, and Advertising Services

The final regulations also clarify how to establish foreign use for sales of digital content and how to establish a recipient's location outside of the United States with respect to electronically supplied services and advertising services. As noted in comments, the proposed regulations did not clearly explain how foreign use should be established for transfers of copyrighted articles that are delivered electronically rather than on a physical medium. To clarify the treatment of these sales, the final regulations specify that a sale of a copyrighted article is evaluated under the general property rules rather than the rules for foreign use of intangible property regardless of how the copyrighted article is transferred. In addition, the final regulations provide new rules for establishing whether a sale of digital content, which may include a sale of a copyrighted article, is for a foreign use. The final regulations define ''digital content'' as a computer program or any other content in digital format. A sale of general property that primarily contains digital content is generally a FDDEI sale if the end user downloads or accesses the content on a device located outside the United States.

In response to comments, the final regulations provide two new subcategories of general services and provide more detailed guidance regarding how to establish the location of recipients of these services. First, the final regulations also provide a new subcategory of general services for electronically supplied services. An electronically supplied service is a general service (other than an advertising service) that is delivered primarily over the internet or an electronic network. As in the case of a digital content sale, an electronically supplied service qualifies for the section 250 deduction if the recipient accesses the service from a location outside the United States. Thus, under the final regulations, the structure of otherwise similar transactions (the sale of digital content and the provision of an electronically supplied service) should generally not affect whether the transaction qualifies for the section 250 deduction. Second, the final regulations provide a new subcategory of general services for advertising services. The final regulations assign the location of the recipient of advertising services at the location where the advertisements are viewed, since that location serves as a reliable proxy for the location of the business recipient that benefits from the service.

The Treasury Department and the IRS project that because taxpayers typically know where digital content, electronically supplied services, and advertising services are accessed or viewed, these provisions will reduce taxpayer compliance costs relative to the proposed regulations.

The Treasury Department and the IRS do not have readily available data or models to provide sufficiently precise estimates of the difference in compliance costs for these items, between the final regulations and regulatory alternatives such as the proposed regulations.

b. Foreign Military Sales

Section 250 conditions eligibility on sales being made to a foreign person and services being provided to a person located outside the United States but does not include specific rules applicable to foreign military sales or services. This silence may lead to inefficient decisions by taxpayers because many sales of military equipment and services by U.S. defense contractors to foreign governments are

structured (pursuant to the Arms Export Control Act) as sales and services provided to the U.S. government. The equipment or services are then sold or provided by the U.S. government to the foreign government; in effect, the contractor is selling goods and services to a foreign person but the sale is technically made to the U.S. government. The Treasury Department and the IRS recognize that the statute is unclear as to whether such sales and services can qualify for the section 250 deduction.

The Treasury Department and the IRS considered several options for treating these sales and services. One option was not addressing this issue in the final regulations. This option was rejected because the Treasury Department and the IRS determined that it would perpetuate uncertainty about the application of section 250 to foreign military sales and services made through the U.S. government and could thus result in inefficient economic activity if some taxpayers took the position that these sales and services qualify for a section 250 deduction but other similarly-situated taxpayers took the position that they do not qualify. Furthermore, to the extent that some taxpayers took the position that these sales and services do not qualify, their economic decisions would be inefficient when evaluated under the intent and purpose of the statute.

A second option was to clarify that a foreign military sale or service through the U.S. government does not qualify for a section 250 deduction. This option was rejected because the Treasury Department and the IRS determined that this treatment would be inconsistent with the intent and purpose of the statute, and thus economic activity would be inefficient when evaluated under this standard.[11]

A third option was to allow any sale or service to a U.S. person that acts as an intermediary and does not take on the benefits and burdens of ownership to generally qualify for a section 250 deduction if there is an ultimate foreign recipient. This option was rejected because the Treasury Department and the IRS determined that such a broad exception could allow multiple section 250 deductions for the same transaction if both the seller and the intermediary buyer were U.S. taxpayers. Furthermore, determining whether a party is an ''intermediary'' for this purpose would require a complex facts-and-circumstances analysis of whether the party had the benefits and burdens of ownership.

A fourth option was the approach adopted in the proposed regulations, which provided that sales of property or the provision of a service to the U.S. government under the Arms Export Control Act is treated as a sale of property or provision of a service to a foreign government and thus generally eligible for the section 250 deduction.

The final regulations adopt the approach provided in the proposed regulations but relax the proposed regulations' documentation requirements. Instead, under the final regulations only the general substantiation requirements apply to these transactions. Thus, the final regulations provide that foreign military sales or services to the U.S. government under the Arms Export Control Act are treated as an eligible sale or service. This rule provides uniform tax treatment between the defense sector and other sectors of the U.S. economy with respect to sales and services that are clearly meant for a foreign use. The final rule also results in lower compliance costs than the proposed regulations because it requires no further substantiation beyond compliance with the Arms Export Control Act rules.

The Treasury Department projects that this reduction in compliance costs will increase foreign military sales and services. The Treasury Department and the IRS have not estimated either the reduction in compliance costs under the final regulations relative to the no-action baseline or regulatory alternatives including the proposed regulations or the change in foreign military sales and services that would result from this reduction. They have not undertaken this estimation because they do not have sufficiently detailed data or models of the costs to taxpayers of establishing that particular transactions are eligible for the section 250 deduction, or the responsiveness of such transactions to compliance costs.

c. Additional Issues and Changes

The final regulations contain several additional changes that will generally expand the situations in which a transaction will be a FDDEI transaction relative to the proposed regulations.

The final regulations add an exception to the rule in the proposed regulations that a property service is a FDDEI service only if the property is located outside the United States for the duration of the period the service is performed. The exception provides that a property service may be a FDDEI service if it is provided with respect to property that is temporarily located in the United States. This will increase the number of property services that constitute FDDEI services relative to the proposed regulations. The final regulations also clarify that the toll manufacturing services are treated as property services. Because of the new exception for property services with respect to property temporarily in the United States, this clarification should increase the number of toll manufacturing and repair, maintenance, and overhaul services that will constitute FDDEI services relative to the proposed regulations. This rule will also mitigate incentives to restructure service contracts into sale contracts (for example by having the property owner sell and buy back the property that requires service) in order to qualify for FDII benefits despite the lack of any economic efficiency gains from doing so. The Treasury Department and the IRS have not estimated the effect of these changes on compliance costs or on the volume of property services or specifically toll manufacturing services that U.S. businesses may undertake relative to the proposed regulations.

The final regulations revise the definition of transportation services to include freight forwarding services because such services are economically similar to the types of shipping services that are already described in the definition of transportation services; this will provide greater certainty to taxpayers that provide these services because the test for determining whether a transportation service is a FDDEI service (based on the origin and destination of the service) will generally be clearer than the test for general services (based on the location of the recipient). The Treasury Department and the IRS have not estimated the effect of this clarification on compliance costs or on the volume of freight forwarding services that U.S. businesses may undertake relative to the proposed regulations.

The final regulations add an exception to the general rule in the proposed regulations that intangible property used in manufacturing is treated as for a foreign use outside the United States only to the extent that the end users of the manufactured property are located outside the United States. The exception allows that a sale of a manufacturing method or process intangible to a foreign unrelated party is for foreign use based on the location of manufacture rather than the location of the ultimate end user. This provides a meaningful reduction in compliance burden relative to the proposed regulations because it does not require

[11] See Joint Comm. on Taxation, General Explanation of Public Law 115–97, at, at 380 n. 1740.

the seller to track the product to its end user and instead relies on information immediately knowable to the seller. The Treasury Department and the IRS have not estimated the effect of this exception on compliance costs or more generally on U.S. economic activity relative to the proposed regulations because we do not have sufficiently precise data on the number of potentially affected taxpayers or the volume of affected activity.

The final regulations eliminate the requirement in the proposed regulations that for sales of international transportation property to be eligible for the section 250 deduction, the property must be located outside the country more than 50 percent of the time and used outside the country for more than 50 percent of the miles for the three-year period after delivery. In the final regulations, the sale of international transportation property is defined to be for a foreign use depending on where it is registered (and in the case of international transportation property not used for compensation or hire, also taking into account where it is primarily hangared or stored). This change in the definition eases the burden of compliance relative to the proposed regulations. The Treasury Department and the IRS have not undertaken quantitative estimates of the effect of this change on compliance costs or on sales of transportation property relative to the proposed regulations.

In response to comments, the final regulations clarify that the definition of general property includes physical commodities that are sold pursuant to derivative contracts. This revision addresses a concern raised in comments that some physical commodities may be sold pursuant to a forward or option contract that itself would not be general property. Also in response to comments, the final regulations provide that the amount of a taxpayer's income from a transaction that is eligible for the section 250 deduction is increased by any gain, or decreased by any loss, taken into account with respect to certain hedging transactions related to the sales. This treatment more accurately reflects the overall economic gain or loss realized with respect to the hedged transactions, and will ensure that similarly-situated taxpayers take consistent positions with respect to these types of transactions. The Treasury Department and the IRS have not estimated the effects of these clarifications relative to the proposed regulations.

Finally, the final regulations remove a special rule from the proposed regulations that a sale of an interest in a foreign branch is treated as giving rise to foreign branch income, which would preclude any income from these sales from giving rise to FDDEI. This change respects the functional difference between income derived by a branch (which generally reflects business activity of the branch) versus income derived by the branch owner from selling the branch (which generally reflects the owner's gain from appreciation in value of the branch), and will allow more transactions to qualify as FDDEI transactions. The Treasury Department and the IRS have not estimated the effects of this change relative to the proposed regulations.

d. Ordering Rule

The Act introduced multiple Code provisions that simultaneously limit the availability of a deduction based, directly or indirectly, upon a taxpayer's taxable income. Because the deductions themselves affect taxable income, the order in which taxpayers calculate deduction limitations matters. The proposed regulations contained an example outlining a possible approach to an ordering rule for these Code provisions. Several comments suggested alternative ordering rules. The Treasury Department and the IRS have decided to further study the most appropriate ordering rule for computations across various provisions that are based upon a taxpayer's taxable income. Therefore, the example from the proposed regulations has been removed and the Treasury Department and the IRS reserve on a final determination of the ordering rule at this time. For now, taxpayers can generally use any reasonable method to determine the ordering of rules that limit deductions based upon taxable income. Because we have decided to study this issue further, we have not yet estimated the economic effects of different potential ordering rules.

2. Economic Effects of Provisions Not Substantially Revised From the 2019 Section 250 Proposed Regulations

a. Computation of the Ratio of FDDEI to DEI

The Act defines a corporation's FDII based on a set of calculations that includes the ratio of its FDDEI to its Deduction Eligible Income (''foreign-derived ratio''). The final regulations specify that, for purposes of determining the numerator of the foreign-derived ratio, the domestic corporation must allocate expenses to its gross FDDEI. The Treasury Department and the IRS deemed this approach the most consistent with the statute by providing what the Treasury Department and the IRS have determined to be the most accurate measure of the corporation's income that is ''foreign-derived,'' through matching of expenses to gross income. In addition, the use of existing expense allocation rules potentially reduces the burden on taxpayers and the IRS relative to adopting a new set of expense allocation rules.

The Treasury Department and the IRS considered two other approaches; one, in which the foreign-derived ratio would be computed as the ratio of foreign versus U.S. gross receipts and another in which the ratio would be computed as foreign versus U.S. gross income. The Treasury Department and the IRS have determined that both of these approaches would result in a less accurate measure of foreign-derived net income. The Treasury Department and the IRS have determined that these alternative approaches could also reward low margin (or even loss-leading) sales or services to foreign markets by allowing a section 250 deduction due to positive gross receipts or income from foreign sources, even if the net income from foreign sources after allocated expenses is zero or negative.

The Treasury Department and the IRS have determined that the chosen alternative generally provides the most accurate computation of FDII. We have not estimated the economic effects of including these alternative, less accurate computations of FDII in the calculation of taxpayers' foreign-derived ratios.

b. Section 962

The section 250 deduction for FDII and GILTI is available only to domestic corporations. However, Congress enacted section 962 in Public Law 89–834 (1962) to ensure that individuals' tax burdens with respect to undistributed foreign earnings of their CFCs are comparable with their tax burdens if they had held their CFCs through a domestic corporation. See S. Rept. 1881, 87th Cong., 2d Sess. 92 (1962).

To address this divergence, the Treasury Department and the IRS considered two options with respect to extending the section 250 deduction to individuals (which include, for this purpose, individual partners in partnerships and individual shareholders in S corporations) that make an election under section 962. The first option was to not allow the deduction for individuals. Not allowing the section 250 deduction would require that individuals that currently own their CFCs directly (or indirectly through a partnership or S corporation) transfer the stock of their CFCs to new U.S.

corporations in order to obtain the benefit of the section 250 deduction. The Treasury Department and the IRS determined that such reorganization would be economically costly, both in terms of legal fees and substantive economic costs related to organizing and operating new corporate entities with no general economic benefit relative to the second option.

The second option was to allow individuals to claim a section 250 deduction with respect to their GILTI if they make the section 962 election. The Treasury Department and the IRS determined that allowing individuals the section 250 deduction would improve economic efficiency by preventing the need for costly legal restructuring solely for the purpose of tax savings. Allowing a section 250 deduction with respect to GILTI of an individual (including an individual that is a shareholder of an S corporation or a partner in a partnership) that makes an election under section 962 provides comparable treatment for this income.

This is the option adopted by the Treasury Department and the IRS in the final regulations.

The Treasury Department and the IRS have not estimated the difference in economic effects between these two regulatory alternatives.

II. Paperwork Reduction Act

The regulations provide the authority for the IRS to require taxpayers to file certain forms with the IRS to obtain the benefit of the section 250 deduction. Pursuant to the regulations, all taxpayers with a section 250 deduction are required to file one new form (Form 8993). The regulations also authorize the IRS to request additional information on several existing forms (Forms 1065 (Schedule K–1), 5471, 5472, 8865, and other forms as needed) if the filer of the form has a deduction under section 250. In 2018, the IRS released and invited comments on drafts of these forms in order to give members of the public advance notice and an opportunity to submit comments. The IRS received no comments on the portions of the forms that relate to section 250 during the comment period. Consequently, the IRS made the forms available in late 2018 for use by the public.

The information collection burdens under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (''PRA'') from these final regulations are in §§ 1.250(a)–1(d), 1.250(b)–1(e)(2), 1.6038–2(f)(15), 1.6038–3(g)(4), and 1.6038A–2(b)(5)(iv). For purposes of the PRA, the reporting burden associated with these collections of information will be reflected in the PRA submission for Form 8993, Form 1065, Form 5471, Form 8865, and Form 5472 (see chart at the end of this part II for OMB control numbers).

The tax forms that were created or revised as a result of the information collections in these final regulations, as well as the estimated number of respondents, are as follows:

RELATED NEW OR REVISED TAX FORMS

	New	Revision of existing form	Number of respondents (estimated)
Form 8993	✓		75,000–350,000
Form 1065, Schedule K–1 (for corporate partners only, revision starting TY2021)		✓	15,000–45,000
Form 5471		✓	10,000–20,000
Form 8865		✓	<10,000
Form 5472		✓	50,000–80,000

Source: RAAS:CDW and ITA.

The numbers of respondents in the Related New or Revised Tax Forms table were estimated by the Research, Applied Analytics and Statistics Division (''RAAS'') of the IRS from the Compliance Data Warehouse (''CDW''), using tax years 2014 through 2017; as well as based on export data from the International Trade Administration (''ITA'') for 2015 and 2016. Tax data for 2018 are not yet available due to extended filing dates. Data for Form 8993 represent preliminary estimates of the total number of taxpayers that may be required to file the new Form 8993. Data for each of the Forms 1065, 5471, 5472, and 8865 represent preliminary estimates of the total number of taxpayers that are expected to file these revised forms regardless of whether that taxpayer must also file Form 8993.

The current status of the PRA submissions related to the tax forms that will be revised as a result of the information collections in the section 250 regulations is provided in the accompanying table. The reporting burdens associated with the information collections in the regulations are included in the aggregated burden estimates for OMB control numbers 1545–0123 (which represents a total estimated burden time for all forms and schedules for corporations of 3.344 billion hours and total estimated monetized costs of $61.558 billion ($2019)), 1545–0074 (which represents a total estimated burden time, including all other related forms and schedules for individuals, of 1.717 billion hours and total estimated monetized costs of $33.267 billion ($2019)), and 1545–1668 (which represents a total estimated burden time for all related forms and schedules for other filers, in particular trusts and estates, of 281,974 hours and total estimated monetized costs of $25.107 million ($2018)). The overall burden estimates provided for the OMB control numbers below are aggregate amounts that relate to the entire package of forms associated with the applicable OMB control number and will in the future include, but not isolate, the estimated burden of the tax forms that will be created or revised as a result of the information collections in the regulations. These numbers are therefore unrelated to the calculations needed to assess the burden imposed by the regulations. These burdens have been reported for other regulations related to the taxation of cross-border income and the Treasury Department and the IRS urge readers to recognize that these numbers are duplicates and to guard against overestimating the burden of the international tax provisions. No burden estimates specific to the forms affected by the regulations are currently available. The Treasury Department and the IRS have not estimated the burden, including that of any new information collections, related to the requirements under the regulations. The Treasury Department and the IRS estimate PRA burdens on a taxpayer-type basis rather than a provision-specific basis. Those estimates would capture both changes made by the Act and those that arise out of discretionary authority exercised in the final regulations.

The Treasury Department and the IRS request comments on all aspects of

information collection burdens related to the final regulations, including estimates for how much time it would take to comply with the paperwork burdens described above for each relevant form and ways for the IRS to minimize the paperwork burden. Proposed revisions (if any) to these forms that reflect the information collections contained in these final regulations will be made available for public comment at *http://www.irs.gov/draftforms* and will not be finalized until after these forms have been approved by OMB under the PRA.

Form	Type of filer	OMB No(s)	Status
Form 8993 (NEW)	Business (NEW Model)	1545–0123.	Published in the **Federal Register** Notice (FRN) on 9/30/19. Public Comment period closed on 11/29/19. Approved by OMB through 12/31/20.
	Link: *https://www.federalregister.gov/documents/2019/09/30/2019-21068/proposed-collection-comment-request-for-forms-1065-1066-1120-1120-c-1120-f-1120-h-1120-nd-1120-s.*		
	Individual (NEW Model)	1545–0074.	Published in the **Federal Register** on 9/30/19. Public Comment period closed on 11/29/19. Approved by OMB through 12/31/20.
	Link: *https://www.federalregister.gov/documents/2019/09/30/2019-21066/proposed-collection-comment-request-for-form-1040-form-1040nr-form-1040nr-ez-form-1040x-1040-sr-and-u.*		
Form 1065, Schedule K–1	Business (NEW Model)	1545–0123.	Published in the **Federal Register** on 9/30/19. Public Comment period closed on 11/29/19. Approved by OMB through 12/31/20.
	Link: *https://www.federalregister.gov/documents/2019/09/30/2019-21068/proposed-collection-comment-request-for-forms-1065-1066-1120-1120-c-1120-f-1120-h-1120-nd-1120-s.*		
Form 5471	Business (NEW Model)	1545–0123.	Published in the **Federal Register** on 9/30/19. Public Comment period closed on 11/29/19. Approved by OMB through 12/31/20.
	Link: *https://www.federalregister.gov/documents/2019/09/30/2019-21068/proposed-collection-comment-request-for-forms-1065-1066-1120-1120-c-1120-f-1120-h-1120-nd-1120-s.*		
Form 8865	All other filers (mainly trusts and estates) (Legacy system).	1545–1668.	Published in the **Federal Register** on 10/01/18. Public Comment period closed on 11/30/18. Approved by OMB through 12/31/21.
	Link: *https://www.federalregister.gov/documents/2018/10/01/2018-21288/proposed-collection-comment-request-for-regulation-project.*		
Form 5472	Business (NEW Model)	1545–0123.	Published in the **Federal Register** on 9/30/19. Public Comment period closed on 11/29/19. Approved by OMB through 12/31/20.
	Link: *https://www.federalregister.gov/documents/2019/09/30/2019-21068/proposed-collection-comment-request-for-forms-1065-1066-1120-1120-c-1120-f-1120-h-1120-nd-1120-s.*		

III. Regulatory Flexibility Act

It is hereby certified that this final regulation will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act (5 U.S.C. chapter 6). The Treasury Department and the IRS have determined that the regulations may affect a substantial number of small entities, but have also concluded that the economic impact on small entities as a result of the collections of information in this regulation is not expected to be significant.

The small business entities that are subject to section 250 and these final regulations are small domestic corporations claiming a deduction under section 250 based on their FDII and GILTI. Pursuant to § 1.250(a)–1(d), taxpayers are required to file new Form 8993 to compute the amount of the eligible deduction for FDII and GILTI under section 250. The Treasury Department and the IRS estimate that there are between 75,000 and 350,000 respondents of all sizes that are likely to file Form 8993. Additionally, under § 1.250(b)–1(e), a partnership that has one or more direct or indirect partners that are domestic corporations and that is required to file a return under section 6031 must furnish on Schedule K–1 (Form 1065) certain information that would allow the partner to accurately calculate its FDII. The Treasury Department and the IRS estimate the number of domestic corporations that are direct or indirect partners in a partnership affected by § 1.250(b)–1(e) is between 15,000 and 45,000.

As discussed in the Summary of Comments and Explanation of Revisions section of this preamble, the Treasury Department and the IRS have determined that requiring specific documentation in every case is challenging given the variations in industry practices. Accordingly, the final regulations adopt a more flexible approach to the documentation requirements in the proposed regulations and, for certain of these regulatory requirements, instead provide substantiation rules that are more flexible with respect to the types of corroborating evidence that may be used to determine that a transaction is a FDDEI transaction. A transaction is a FDDEI transaction only if the taxpayer

substantiates its determination of foreign use (in the case of sales of general property to non-end users and sales of intangible property) or location outside the United States (in the case of general services provided to a business recipient) as described in the applicable paragraph of § 1.250(b)–4(d)(3) or § 1.250(b)–5(e)(4). Similar to the exception for small businesses from the documentation requirements in the proposed regulations, the final regulations provide that the new specific substantiation requirements do not apply to a taxpayer if the taxpayer and all related parties of the taxpayer received less than $25,000,000 in gross receipts in the prior taxable year. The Treasury Department and the IRS anticipate that a substantial share of small entities claiming a section 250 deduction will qualify for the small business exception, thereby significantly reducing the overall burden of the final regulations on small entities. Although the rule will alleviate burden on many small entities, the Small Business Administration's small business size standards (13 CFR part 121) identify as small entities several industries with annual revenues above $25 million.

For the rules in the final regulations for which there are no specific substantiation requirements, taxpayers will continue to be required to substantiate deductions under section 250 pursuant to section 6001. Small business entities are expected to experience 0 to 5 minutes, with an average of 2.5 minutes, of recordkeeping per transaction recipient. The hourly estimates include all associated activities: Recordkeeping, tax planning, learning about the law, gathering tax materials, form completion and submissions, and time with a tax preparer or use of tax software. The estimated monetized burden for small business entities for compliance is $53.12 per hour, a figure computed from the IRS Business Taxpayer Burden model which assigns each firm in the micro data a monetization rate based on total revenue and assets reported on their tax return. See ''Tax Compliance Burden'' (John Guyton et al., July 2018) at *https://www.irs.gov/pub/irs-soi/d13315.pdf.* The assigned monetization rates include, in addition to wages, employer non-wage costs such as employment taxes, benefits, and overhead. The reporting burden for completing Form 8993 is estimated to average 21 hours for all affected entities, regardless of size. The reporting burden on small entities (those with receipts below $25 million in RAAS calculations) is estimated to average 17.1 hours. Based on the monetized hourly burden reported above, the annual per-entity reporting burden for small entities will be $908.

For these reasons, the Treasury Department and the IRS have determined that the requirements in §§ 1.250(a)–1(d), 1.250(b)–4(d)(3), and 1.250(b)–5(e)(4) will not have a significant economic impact on a substantial number of small entities.

The small business entities that are subject to § 1.6038–2(f)(15), § 1.6038–3(g)(4), or § 1.6038A–2(b)(5)(iv) are domestic small business entities that claim a deduction under section 250 by reason of having FDII that are either controlling U.S. shareholders of a foreign corporation, controlling fifty-percent partners or controlling ten-percent partners of a foreign partnership, or at least 25-percent foreign-owned, by vote or value, respectively. The data to assess the number of small entities potentially affected by § 1.6038–2(f)(15), § 1.6038–3(g)(4), or § 1.6038A–2(b)(5)(iv) are not readily available. However, businesses that are controlling U.S. shareholders of a foreign corporation, controlling fifty-percent partners or controlling ten-percent partners of a foreign partnership, or at least 25-percent foreign-owned, by vote or value are generally not small businesses for the reasons described in part III of the Special Analyses section in the proposed regulation (REG–104464–18, 84 FR 8188 (March 6, 2019)). Consequently, the Treasury Department and the IRS have determined that §§ 1.6038–2(f)(15), 1.6038–3(g)(4), and 1.6038A–2(b)(5)(iv) will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f) of the Code, the proposed regulations preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses. No comments were received.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. These regulations do not have federalism implications and do not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

VI. Congressional Review Act

The Administrator of the Office of Information and Regulatory Affairs of OMB has determined that this Treasury decision is a major rule for purposes of the Congressional Review Act (5 U.S.C. 801 *et seq.*) (''CRA''). Under section 801(a)(3) of the CRA, a major rule generally may not take effect until 60 days after the rule is published in the **Federal Register**. Accordingly, the Treasury Department and IRS are adopting these final regulations with the delayed effective date generally prescribed under the Congressional Review Act.

Drafting Information

The principal authors of the regulations are Kenneth Jeruchim, Brad McCormack, and Lorraine Rodriguez of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in the development of the regulations.

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings, Notices, and other guidance cited in this document are published in the Internal Revenue Bulletin and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order for §§ 1.250–0, 1.250–1, 1.250(a)–1, 1.250(b)–1, 1.250(b)–2, 1.250(b)–3, 1.250(b)–4, 1.250(b)–5, 1.250(b)–6, and § 1.1502–50 and revising the entries for §§ 1.1502–12 and 1.1502–13 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 1.250–0 also issued under 26 U.S.C. 250(c).

Section 1.250–1 also issued under 26 U.S.C. 250(c).

Section 1.250(a)–1 also issued under 26 U.S.C. 250(c) and 6001.

Section 1.250(b)–1 also issued under 26 U.S.C. 250(c) and 6001.

Section 1.250(b)–2 also issued under 26 U.S.C. 250(c).

Section 1.250(b)–3 also issued under 26 U.S.C. 250(c).

Section 1.250(b)–4 also issued under 26 U.S.C. 250(c).

Section 1.250(b)–5 also issued under 26 U.S.C. 250(c).

Section 1.250(b)–6 also issued under 26 U.S.C. 250(c).

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Section 1.1502–12 also issued under 26 U.S.C. 250(c) and 1502.

Section 1.1502–13 also issued under 26 U.S.C. 250(c) and 1502.

* * * * *

Section 1.1502–50 also issued under 26 U.S.C. 250(c) and 1502.

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■ **Par. 2.** Sections 1.250–0, 1.250–1, 1.250(a)–1, and 1.250(b)–1 through 1.250(b)–6 are added to read as follows:

Sec.

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§ 1.250–0 Table of contents.

This section contains a listing of the headings for §§ 1.250–1, 1.250(a)–1, and 1.250(b)–1 through 1.250(b)–6.

§ 1.250–1 Introduction.

(a) *Overview.* Sections 1.250(a)–1 and 1.250(b)–1 through 1.250(b)–6 provide rules to determine a domestic corporation's section 250 deduction. Section 1.250(a)–1 provides rules to determine the amount of a domestic corporation's deduction for foreign-derived intangible income and global intangible low-taxed income. Section 1.250(b)–1 provides general rules and definitions regarding the computation of foreign-derived intangible income. Section 1.250(b)–2 provides rules for determining a domestic corporation's qualified business asset investment. Section 1.250(b)–3 provides general rules and definitions regarding the determination of gross foreign-derived deduction eligible income. Section 1.250(b)–4 provides rules regarding the determination of gross foreign-derived deduction eligible income from the sale of property. Section 1.250(b)–5 provides rules regarding the determination of gross foreign-derived deduction eligible income from the provision of a service. Section 1.250(b)–6 provides rules regarding the sale of property or provision of a service to a related party.

(b) *Applicability dates.* Except as provided in the next sentence, §§ 1.250(a)–1 and 1.250(b)–1 through 1.250(b)–6 apply to taxable years beginning on or after January 1, 2021. Section 1.250(b)–2(h) applies to taxable years ending on or after March 4, 2019. However, taxpayers may choose to apply §§ 1.250(a)–1 and 1.250(b)–1 through 1.250(b)–6 for taxable years beginning on or after January 1, 2018, and before January 1, 2021, provided they apply the regulations in their entirety (other than § 1.250(b)–3(f) and the applicable provisions in § 1.250(b)–4(d)(3) or § 1.250(b)–5(e)(4)).

§ 1.250(a)–1 Deduction for foreign-derived intangible income (FDII) and global intangible low-taxed income (GILTI).

(a) *Scope.* This section provides rules for determining the amount of a domestic corporation's deduction for

foreign-derived intangible income (FDII) and global intangible low-taxed income (GILTI). Paragraph (b) of this section provides general rules for determining the amount of the deduction. Paragraph (c) of this section provides definitions relevant for determining the amount of the deduction. Paragraph (d) of this section provides reporting requirements for a domestic corporation claiming the deduction. Paragraph (e) of this section provides a rule for determining the amount of the deduction of a member of a consolidated group. Paragraph (f) of this section provides examples illustrating the application of this section.

(b) *Allowance of deduction*—(1) *In general.* A domestic corporation is allowed a deduction for any taxable year equal to the sum of—

(i) 37.5 percent of its foreign-derived intangible income for the year; and

(ii) 50 percent of—

(A) Its global intangible low-taxed income for the year; and

(B) The amount treated as a dividend received by the corporation under section 78 which is attributable to its GILTI for the year.

(2) *Taxable income limitation.* In the case of a domestic corporation with a section 250(a)(2) amount for a taxable year, for purposes of applying paragraph (b)(1) of this section for the year—

(i) The corporation's FDII for the year (if any) is reduced (but not below zero) by an amount that bears the same ratio to the corporation's section 250(a)(2) amount that the corporation's FDII for the year bears to the sum of the corporation's FDII and GILTI for the year; and

(ii) The corporation's GILTI for the year (if any) is reduced (but not below zero) by the excess of the corporation's section 250(a)(2) amount over the amount of the reduction described in paragraph (b)(2)(i) of this section.

(3) *Reduction in deduction for taxable years after 2025.* For any taxable year of a domestic corporation beginning after December 31, 2025, paragraph (b)(1) of this section applies by substituting—

(i) 21.875 percent for 37.5 percent in paragraph (b)(1)(i) of this section; and

(ii) 37.5 percent for 50 percent in paragraph (b)(1)(ii) of this section.

(4) *Treatment under section 4940.* For purposes of section 4940(c)(3)(A), a deduction under section 250(a) is not treated as an ordinary and necessary expense paid or incurred for the production or collection of gross investment income.

(c) *Definitions.* The following definitions apply for purposes of this section.

(1) *Domestic corporation.* The term *domestic corporation* has the meaning set forth in section 7701(a), but does not include a regulated investment company (as defined in section 851), a real estate investment trust (as defined in section 856), or an S corporation (as defined in section 1361).

(2) *Foreign-derived intangible income (FDII).* The term *foreign-derived intangible income* or *FDII* has the meaning set forth in § 1.250(b)–1(b).

(3) *Global intangible low-taxed income (GILTI).* The term *global intangible low-taxed income* or *GILTI* means, with respect to a domestic corporation for a taxable year, the corporation's GILTI inclusion amount under § 1.951A–1(c) for the taxable year.

(4) *Section 250(a)(2) amount.* The term *section 250(a)(2) amount* means, with respect to a domestic corporation for a taxable year, the excess (if any) of the sum of the corporation's FDII and GILTI (determined without regard to section 250(a)(2) and paragraph (b)(2) of this section), over the corporation's taxable income. For a corporation that is subject to the unrelated business income tax under section 511, taxable income is determined only by reference to that corporation's unrelated business taxable income defined under section 512.

(5) *Taxable income*—(i) *In general.* The term *taxable income* has the meaning set forth in section 63(a) determined without regard to the deduction allowed under section 250 and this section.

(ii) [Reserved]

(d) *Reporting requirement.* Each domestic corporation (or individual making an election under section 962) that claims a deduction under section 250 for a taxable year must make an annual return on Form 8993, ''Section 250 Deduction for Foreign-Derived Intangible Income (FDII) and Global Intangible Low-Taxed Income (GILTI)'' (or any successor form) for such year, setting forth the information, in such form and manner, as Form 8993 (or any successor form) or its instructions prescribe. Returns on Form 8993 (or any successor form) for a taxable year must be filed with the domestic corporation's (or in the case of a section 962 election, the individual's) income tax return on or before the due date (taking into account extensions) for filing the corporation's (or in the case of a section 962 election, the individual's) income tax return.

(e) *Determination of deduction for consolidated groups.* A member of a consolidated group (as defined in § 1.1502–1(h)) determines its deduction under section 250(a) and this section under the rules provided in § 1.1502–50(b).

(f) *Example: Application of the taxable income limitation.* The following example illustrates the application of this section. For purposes of the example, it is assumed that DC is a domestic corporation that is not a member of a consolidated group and the taxable year of DC begins after 2017 and before 2026.

(1) *Facts.* For the taxable year, without regard to section 250(a)(2) and paragraph (b)(2) of this section, DC has FDII of $100x and GILTI of $300x. DC's taxable income (without regard to section 250(a) and this section) is $300x.

(2) *Analysis.* DC has a section 250(a)(2) amount of $100x, which is equal to the excess of the sum of DC's FDII and GILTI of $400x ($100x + $300x) over its taxable income of $300x. As a result, DC's FDII and GILTI are reduced, in the aggregate, by $100x under section 250(a)(2) and paragraph (b)(2) of this section for purposes of calculating DC's deduction allowed under section 250(a)(1) and paragraph (b)(1) of this section. DC's FDII is reduced by $25x, the amount that bears the same ratio to the section 250(a)(2) amount ($100x) as DC's FDII ($100x) bears to the sum of DC's FDII and GILTI ($400x). DC's GILTI is reduced by $75x, which is the remainder of the section 250(a)(2) amount ($100x − $25x). Therefore, for purposes of calculating its deduction under section 250(a)(1) and paragraph (b)(1) of this section, DC's FDII is $75x ($100x − $25x) and its GILTI is $225x ($300x − $75x). Accordingly, DC is allowed a deduction for the taxable year under section 250(a)(1) and paragraph (b)(1) of this section of $140.63x ($75x × 0.375 + $225x × 0.50).

§ 1.250(b)–1 Computation of foreign-derived intangible income (FDII).

(a) *Scope.* This section provides rules for computing FDII. Paragraph (b) of this section defines FDII. Paragraph (c) of this section provides definitions that are relevant for computing FDII. Paragraph (d) of this section provides rules for computing gross income and allocating and apportioning deductions for purposes of computing deduction eligible income (DEI) and foreign-derived deduction eligible income (FDDEI). Paragraph (e) of this section provides rules for computing the DEI and FDDEI of a domestic corporate partner. Paragraph (f) of this section provides a rule for computing the FDII of a member of a consolidated group. Paragraph (g) of this section provides a rule for computing the FDII of a tax-exempt corporation.

(b) *Definition of FDII.* Subject to the provisions of this section, the term *FDII* means, with respect to a domestic corporation for a taxable year, the corporation's deemed intangible income for the year multiplied by the

corporation's foreign-derived ratio for the year.

(c) *Definitions.* This paragraph (c) provides definitions that apply for purposes of this section and §§ 1.250(b)–2 through 1.250(b)–6.

(1) *Controlled foreign corporation.* The term *controlled foreign corporation* has the meaning set forth in section 957(a) and § 1.957–1(a).

(2) *Deduction eligible income.* The term *deduction eligible income* or *DEI* means, with respect to a domestic corporation for a taxable year, the excess (if any) of the corporation's gross DEI for the year over the deductions properly allocable to gross DEI for the year, as determined under paragraph (d)(2) of this section.

(3) *Deemed intangible income.* The term *deemed intangible income* means, with respect to a domestic corporation for a taxable year, the excess (if any) of the corporation's DEI for the year over the corporation's deemed tangible income return for the year.

(4) *Deemed tangible income return.* The term *deemed tangible income return* means, with respect to a domestic corporation and a taxable year, 10 percent of the corporation's qualified business asset investment for the year.

(5) *Dividend.* The term *dividend* has the meaning set forth in section 316, and includes any amount treated as a dividend under any other provision of subtitle A of the Internal Revenue Code or the regulations in this part (for example, under section 78, 356(a)(2), 367(b), or 1248).

(6) *Domestic corporation.* The term *domestic corporation* has the meaning set forth in § 1.250(a)–1(c)(1).

(7) *Domestic oil and gas extraction income.* The term *domestic oil and gas extraction income* means income described in section 907(c)(1), substituting ''within the United States'' for ''without the United States.''

(8) *FDDEI sale.* The term *FDDEI sale* has the meaning set forth in § 1.250(b)–4(b).

(9) *FDDEI service.* The term *FDDEI service* has the meaning set forth in § 1.250(b)–5(b).

(10) *FDDEI transaction.* The term *FDDEI transaction* means a FDDEI sale or a FDDEI service.

(11) *Foreign branch income.* The term *foreign branch income* has the meaning set forth in section 904(d)(2)(J) and § 1.904–4(f)(2).

(12) *Foreign-derived deduction eligible income.* The term *foreign-derived deduction eligible income* or *FDDEI* means, with respect to a domestic corporation for a taxable year, the excess (if any) of the corporation's gross FDDEI for the year, over the deductions properly allocable to gross FDDEI for the year, as determined under paragraph (d)(2) of this section.

(13) *Foreign-derived ratio.* The term *foreign-derived ratio* means, with respect to a domestic corporation for a taxable year, the ratio (not to exceed one) of the corporation's FDDEI for the year to the corporation's DEI for the year. If a domestic corporation has no FDDEI for a taxable year, the corporation's foreign-derived ratio is zero for the taxable year.

(14) *Gross RDEI.* The term *gross RDEI* means, with respect to a domestic corporation or a partnership for a taxable year, the portion of the corporation or partnership's gross DEI for the year that is not included in gross FDDEI.

(15) *Gross DEI.* The term *gross DEI* means, with respect to a domestic corporation or a partnership for a taxable year, the gross income of the corporation or partnership for the year determined without regard to the following items of gross income—

(i) Amounts included in gross income under section 951(a)(1);

(ii) GILTI (as defined in § 1.250(a)–1(c)(3));

(iii) Financial services income (as defined in section 904(d)(2)(D) and § 1.904–4(e)(1)(ii));

(iv) Dividends received from a controlled foreign corporation with respect to which the corporation or partnership is a United States shareholder;

(v) Domestic oil and gas extraction income; and

(vi) Foreign branch income.

(16) *Gross FDDEI.* The term *gross FDDEI* means, with respect to a domestic corporation or a partnership for a taxable year, the portion of the gross DEI of the corporation or partnership for the year which is derived from all of its FDDEI transactions.

(17) *Modified affiliated group*—(i) *In general.* The term *modified affiliated group* means an affiliated group as defined in section 1504(a) determined by substituting ''more than 50 percent'' for ''at least 80 percent'' each place it appears, and without regard to section 1504(b)(2) and (3).

(ii) *Special rule for noncorporate entities.* Any person (other than a corporation) that is controlled by one or more members of a modified affiliated group (including one or more persons treated as a member or members of a modified affiliated group by reason of this paragraph (c)(17)(ii)) or that controls any such member is treated as a member of the modified affiliated group.

(iii) *Definition of control.* For purposes of paragraph (c)(17)(ii) of this section, the term *control* has the meaning set forth in section 954(d)(3).

(18) *Qualified business asset investment.* The term *qualified business asset investment* or *QBAI* has the meaning set forth in § 1.250(b)–2(b).

(19) *Related party.* The term *related party* means, with respect to any person, any member of a modified affiliated group that includes such person.

(20) *United States shareholder.* The term *United States shareholder* has the meaning set forth in section 951(b) and § 1.951–1(g).

(d) *Treatment of cost of goods sold and allocation and apportionment of deductions*—(1) *Cost of goods sold for determining gross DEI and gross FDDEI.* For purposes of determining the gross income included in gross DEI and gross FDDEI of a domestic corporation or a partnership, the cost of goods sold of the corporation or partnership is attributed to gross receipts with respect to gross DEI or gross FDDEI under any reasonable method that is applied consistently. Cost of goods sold must be attributed to gross receipts with respect to gross DEI or gross FDDEI regardless of whether certain costs included in cost of goods sold can be associated with activities undertaken in an earlier taxable year (including a year before the effective date of section 250). A domestic corporation or partnership may not segregate cost of goods sold with respect to a particular product into component costs and attribute those component costs disproportionately to gross receipts with respect to amounts excluded from gross DEI or gross FDDEI, as applicable.

(2) *Deductions properly allocable to gross DEI and gross FDDEI*—(i) *In general.* For purposes of determining a domestic corporation's deductions that are properly allocable to gross DEI and gross FDDEI, the corporation's deductions are allocated and apportioned to gross DEI and gross FDDEI under the rules of §§ 1.861–8 through 1.861–14T and 1.861–17 by treating section 250(b) as an operative section described in § 1.861–8(f). In allocating and apportioning deductions under §§ 1.861–8 through 1.861–14T and 1.861–17, gross FDDEI and gross RDEI are treated as separate statutory groupings. The deductions allocated and apportioned to gross DEI equal the sum of the deductions allocated and apportioned to gross FDDEI and gross RDEI. All items of gross income described in paragraphs (c)(15)(i) through (vi) of this section are in the residual grouping.

(ii) *Determination of deductions to allocate.* For purposes of determining the deductions of a domestic corporation for a taxable year properly allocable to gross DEI and gross FDDEI, the deductions of the corporation for the taxable year are determined without regard to sections 163(j), 170(b)(2), 172, 246(b), and 250.

(3) *Examples.* The following examples illustrate the application of this paragraph (d).

(i) *Assumed facts.* The following facts are assumed for purposes of the examples—

(A) DC is a domestic corporation that is not a member of a consolidated group.

(B) All sales and services are provided to persons that are not related parties.

(C) All sales and services to foreign persons qualify as FDDEI transactions.

(ii) *Examples*—

(A) *Example 1: Allocation of deductions*—(*1*) *Facts.* For a taxable year, DC manufactures products A and B in the United States. DC sells products A and B and provides services associated with products A and B to United States and foreign persons. DC's QBAI for the taxable year is $1,000x. DC has $300x of deductible interest expense allowed under section 163. DC has assets with a tax book value of $2,500x. The tax book value of DC's assets used to produce products A and B and services is split evenly between assets that produce gross FDDEI and assets that produce gross RDEI. DC has $840x of supportive deductions, as defined in § 1.861–8(b)(3), attributable to general and administrative expenses incurred for the purpose of generating the class of gross income that consists of gross DEI. DC apportions the $840x of deductions on the basis of gross income in accordance with § 1.861–8T(c)(1). For purposes of determining gross FDDEI and gross DEI under paragraph (d)(1) of this section, DC attributes $200x of cost of goods sold to Product A and $400x of cost of goods sold to Product B, and then attributes the cost of goods sold for each product ratably between the gross receipts of such product sold to foreign persons and the gross receipts of such product sold to United States persons. The manner in which DC attributes the cost of goods sold is a reasonable method. DC has no other items of income, loss, or deduction. For the taxable year, DC has the following income tax items relevant to the determination of its FDII:

TABLE 1 TO PARAGRAPH (d)(3)(ii)(A)(*1*)

	Product A	Product B	Services	Total
Gross receipts from U.S. persons	$200x	$800x	$100x	$1,100x
Gross receipts from foreign persons	200x	800x	100x	1,100x
Total gross receipts	400x	1,600x	200x	2,200x
Cost of goods sold for gross receipts from U.S. persons	100x	200x	0	300x
Cost of goods sold for gross receipts from foreign persons	100x	200x	0	300x
Total cost of goods sold	200x	400x	0	600x
Gross income	200x	1,200x	200x	1,600x
Tax book value of assets used to produce products/services	500x	500x	1,500x	2,500x

(*2*) *Analysis*—(*i*) *Determination of gross FDDEI and gross RDEI.* Because DC does not have any income described in section 250(b)(3)(A)(i)(I) through (VI) and paragraphs (c)(15)(i) through (vi) of this section, none of its gross income is excluded from gross DEI. DC's gross DEI is $1,600x ($2,200x total gross receipts less $600x total cost of goods sold). DC's gross FDDEI is $800x ($1,100x of gross receipts from foreign persons minus attributable cost of goods sold of $300x).

(*ii*) *Determination of foreign-derived deduction eligible income.* To calculate its FDDEI, DC must determine the amount of its deductions that are allocated and apportioned to gross FDDEI and then subtract those amounts from gross FDDEI. DC's interest deduction of $300x is allocated and apportioned to gross FDDEI on the basis of the average total value of DC's assets in each grouping. DC has assets with a tax book value of $2,500x split evenly between assets that produce gross FDDEI and assets that produce gross RDEI. Accordingly, an interest expense deduction of $150x is apportioned to DC's gross FDDEI. With respect to DC's supportive deductions of $840x that are related to DC's gross DEI, DC apportions such deductions between gross FDDEI and gross RDEI on the basis of gross income. Accordingly, supportive deductions of $420x are apportioned to DC's gross FDDEI. Thus, DC's FDDEI is $230x, which is equal to its gross FDDEI of $800x less $150x of interest expense deduction and $420x of supportive deductions.

(*iii*) *Determination of deemed intangible income.* DC's deemed tangible income return is $100x, which is equal to 10 percent of its QBAI of $1,000x. DC's DEI is $460x, which is equal to its gross DEI of $1,600x less $300x of interest expense deductions and $840x of supportive deductions. Therefore, DC's deemed intangible income is $360x, which is equal to the excess of its DEI of $460x over its deemed tangible income return of $100x.

(*iv*) *Determination of foreign-derived intangible income.* DC's foreign-derived ratio is 50 percent, which is the ratio of DC's FDDEI of $230x to DC's DEI of $460x. Therefore, DC's FDII is $180x, which is equal to DC's deemed intangible income of $360x multiplied by its foreign-derived ratio of 50 percent.

(B) *Example 2: Allocation of deductions with respect to a partnership*—(*1*) *Facts*—(*i*) *DC's operations.* DC is engaged in the production and sale of products consisting of two separate product groups in three-digit Standard Industrial Classification (SIC) Industry Groups, hereafter referred to as Group AAA and Group BBB. All of the gross income of DC is included in gross DEI. DC incurs $250x of research and experimental (R&E) expenditures in the United States that are deductible under section 174. None of the R&E is included in cost of goods sold. For purposes of determining gross FDDEI and gross DEI under paragraph (d)(1) of this section, DC attributes $210x of cost of goods sold to Group AAA products and $900x of cost of goods sold to Group BBB products, and then attributes the cost of goods sold with respect to each such product group ratably between the gross receipts with respect to such product group sold to foreign persons and the gross receipts with respect to such product group not sold to foreign persons. The manner in which DC attributes the cost of goods sold is a reasonable method. For the taxable year, DC has the following income tax items relevant to the determination of its FDII:

TABLE 2 TO (d)(3)(ii)(B)(*1*)(*i*)

	Group AAA products	Group BBB products	Total
Gross receipts from U.S. persons	$200x	$800x	$1,000x
Gross receipts from foreign persons	100x	400x	500x
Total gross receipts	300x	1,200x	1,500x
Cost of goods sold for gross receipts from U.S. persons	140x	600x	740x
Cost of goods sold for gross receipts from foreign persons	70x	300x	370x
Total cost of goods sold	210x	900x	1,110x

TABLE 2 TO (d)(3)(ii)(B)(*1*)(*i*)—Continued

	Group AAA products	Group BBB products	Total
Gross income	90x	300x	390x
R&E deductions	40x	210x	250x

(*ii*) *PRS's operations.* In addition to its own operations, DC is a partner in PRS, a partnership that also produces products described in SIC Group AAA. DC is allocated 50 percent of all income, gain, loss, and deductions of PRS. During the taxable year, PRS sells Group AAA products solely to foreign persons, and all of its gross income is included in gross DEI. PRS has $400 of gross receipts from sales of Group AAA products for the taxable year and incurs $100x of research and experimental (R&E) expenditures in the United States that are deductible under section 174. None of the R&E is included in cost of goods sold. For purposes of determining gross FDDEI and gross DEI under paragraph (d)(1) of this section, PRS attributes $200x of cost of goods sold to Group AAA products, and then attributes the cost of goods sold with respect to such product group ratably between the gross receipts with respect to such product group sold to foreign persons and the gross receipts with respect to such product group not sold to foreign persons. The manner in which PRS attributes the cost of goods sold is a reasonable method. DC's distributive share of PRS taxable items is $100x of gross income and $50x of R&E deductions, and DC's share of PRS's gross receipts from sales of Group AAA products for the taxable year is $200x under § 1.861–17(f)(3).

(*iii*) *Application of the sales method to allocate and apportion R&E.* DC applies the sales method to apportion its R&E deductions under § 1.861–17. Neither DC nor PRS licenses or sells its intangible property to controlled or uncontrolled corporations in a manner that necessitates including the sales by such corporations for purposes of apportioning DC's R&E deductions.

(*2*) *Analysis*—(*i*) *Determination of gross DEI and gross FDDEI.* Under paragraph (e)(1) of this section, DC's gross DEI, gross FDDEI, and deductions allocable to those amounts include its distributive share of gross DEI, gross FDDEI, and deductions of PRS. Thus, DC's gross DEI for the year is $490x ($390x attributable to DC and $100x attributable to DC's interest in PRS). DC's gross income from sales of Group AAA products to foreign persons is $30x ($100x of gross receipts minus attributable cost of goods sold of $70x). DC's gross income from sales of Group BBB products to foreign persons is $100x ($400x of gross receipts minus attributable cost of goods sold of $300x). DC's gross FDDEI for the year is $230x ($30x from DC's sale of Group AAA products plus $100x from DC's sale of Group BBB products plus DC's distributive share of PRS's gross FDDEI of $100x).

(*ii*) *Allocation and apportionment of R&E deductions.* To determine FDDEI, DC must allocate and apportion its R&E expense of $300x ($250x incurred directly by DC and $50x incurred indirectly through DC's interest in PRS). In accordance with § 1.861–17, R&E expenses are first allocated to a class of gross income related to a three-digit SIC group code. DC's R&E expenses related to products in Group AAA are $90x ($40x incurred directly by DC and $50x incurred indirectly through DC's interest in PRS) and its expenses related to Group BBB are $210x. See paragraph (d)(2)(i) of this section. Accordingly, all R&E expense attributable to a particular SIC group code is apportioned on the basis of the amounts of sales within that SIC group code. Total sales within Group AAA were $500x ($300x directly by DC and $200x attributable to DC's interest in PRS), $300x of which were made to foreign persons ($100x directly by DC and $200x attributable to DC's interest in PRS). Therefore, the $90x of R&E expense related to Group AAA is apportioned $54x to gross FDDEI ($90x × $300x/$500x) and $36x to gross RDEI ($90x × $200x/$500x). Total sales within Group BBB were $1,200x, $400x of which were made to foreign persons. Therefore, the $210x of R&E expense related to products in Group BBB is apportioned $70x to gross FDDEI ($210x × $400x/$1,200x) and $140x to gross RDEI ($210x × $800x/$1,200x). Accordingly, DC's FDDEI for the tax year is $106x ($230x gross FDDEI minus $124x of R&E ($54x + $70x) allocated and apportioned to gross FDDEI).

(e) *Domestic corporate partners*—(1) *In general.* A domestic corporation's DEI and FDDEI for a taxable year are determined by taking into account the corporation's share of gross DEI, gross FDDEI, and deductions of any partnership (whether domestic or foreign) in which the corporation is a direct or indirect partner. For purposes of the preceding sentence, a domestic corporation's share of each such item of a partnership is determined in accordance with the corporation's distributive share of the underlying items of income, gain, deduction, and loss of the partnership that comprise such amounts. See § 1.250(b)–2(g) for rules on calculating the increase to a domestic corporation's QBAI by the corporation's share of partnership QBAI.

(2) *Reporting requirement for partnership with domestic corporate partners.* A partnership that has one or more direct partners that are domestic corporations and that is required to file a return under section 6031 must furnish to each such partner on or with such partner's Schedule K–1 (Form 1065 or any successor form) by the due date (including extensions) for furnishing Schedule K–1 the partner's share of the partnership's gross DEI, gross FDDEI, deductions that are properly allocable to the partnership's gross DEI and gross FDDEI, and partnership QBAI (as determined under § 1.250(b)–2(g)) for each taxable year in which the partnership has gross DEI, gross FDDEI, deductions that are properly allocable to the partnership's gross DEI or gross FDDEI, or partnership specified tangible property (as defined in § 1.250(b)–2(g)(5)). In the case of tiered partnerships where one or more partners of an upper-tier partnership are domestic corporations, a lower-tier partnership must report the amount specified in this paragraph (e)(2) to the upper-tier partnership to allow reporting of such information to any partner that is a domestic corporation. To the extent that a partnership cannot determine the information described in the first sentence of this paragraph (e)(2), the partnership must instead furnish to each partner its share of the partnership's attributes that a partner needs to determine the partner's gross DEI, gross FDDEI, deductions that are properly allocable to the partner's gross DEI and gross FDDEI, and the partner's adjusted bases in partnership specified tangible property.

(3) *Examples.* The following examples illustrate the application of this paragraph (e).

(i) *Assumed facts.* The following facts are assumed for purposes of the examples—

(A) DC, a domestic corporation, is a partner in PRS, a partnership.

(B) FP and FP2 are foreign persons.

(C) FC is a foreign corporation.

(D) The allocations under PRS's partnership agreement satisfy the requirements of section 704.

(E) No partner of PRS is a related party of DC.

(F) DC, PRS, and FC all use the calendar year as their taxable year.

(G) PRS has no items of income, loss, or deduction for its taxable year, except the items of income described.

(ii) *Examples*—

(A) *Example 1: Sale by partnership to foreign person*—(*1*) *Facts.* Under the terms of the partnership agreement, DC is allocated 50 percent of all income, gain, loss, and deductions of PRS. For the taxable year, PRS recognizes $20x of gross income on the sale of general property (as defined in § 1.250(b)–

3(b)(10)) to FP, a foreign person (as determined under § 1.250(b)–4(c)), for a foreign use (as determined under § 1.250(b)–4(d)). The gross income recognized on the sale of property is not described in section 250(b)(3)(A)(I) through (VI) or paragraphs (c)(15)(i) through (vi) of this section.

(*2*) *Analysis.* PRS's sale of property to FP is a FDDEI sale as described in § 1.250(b)–4(b). Therefore, the gross income derived from the sale ($20x) is included in PRS's gross DEI and gross FDDEI, and DC's share of PRS's gross DEI and gross FDDEI ($10x) is included in DC's gross DEI and gross FDDEI for the taxable year.

(B) *Example 2: Sale by partnership to foreign person attributable to foreign branch*—(*1*) *Facts.* The facts are the same as in paragraph (e)(3)(ii)(A)(*1*) of this section (the facts in *Example 1*), except the income from the sale of property to FP is attributable to a foreign branch of PRS.

(*2*) *Analysis.* PRS's sale of property to FP is excluded from PRS's gross DEI under section 250(b)(3)(A)(VI) and paragraph (c)(15)(vi) of this section. Accordingly, DC's share of PRS's gross income of $10x from the sale is not included in DC's gross DEI or gross FDDEI for the taxable year.

(C) *Example 3: Partnership with a loss in gross FDDEI*—(*1*) *Facts.* The facts are the same as in paragraph (e)(3)(ii)(A)(*1*) of this section (the facts in *Example 1*), except that in the same taxable year, PRS also sells property to FP2, a foreign person (as determined under § 1.250(b)–4(c)), for a foreign use (as determined under § 1.250(b)–4(d)). After taking into account both sales, PRS has a gross loss of $30x.

(*2*) *Analysis.* Both the sale of property to FP and the sale of property to FP2 are FDDEI sales because each sale is described in § 1.250(b)–4(b). DC's share of PRS's gross loss ($15x) from the sales is included in DC's gross DEI and gross FDDEI.

(D) *Example 4: Sale by partnership to foreign related party of the partnership*—(*1*) *Facts.* Under the terms of the partnership agreement, DC has 25 percent of the capital and profits interest in the partnership and is allocated 25 percent of all income, gain, loss, and deductions of PRS. PRS owns 100 percent of the single class of stock of FC. In the taxable year, PRS has $20x of gain on the sale of general property (as defined in § 1.250(b)–3(b)(10)) to FC, and FC makes a physical and material change to the property within the meaning of § 1.250(b)–4(d)(1)(iii)(B) outside the United States before selling the property to customers in the United States.

(*2*) *Analysis.* The sale of property by PRS to FC is described in § 1.250(b)–4(b) without regard to the application of § 1.250(b)–6, since the sale is to a foreign person (as determined under § 1.250(b)–4(c)) for a foreign use (as determined under § 1.250(b)–4(d)). However, FC is a foreign related party of PRS within the meaning of section 250(b)(5)(D) and § 1.250(b)–3(b)(6), because FC and PRS are members of a modified affiliated group within the meaning of paragraph (c)(17) of this section. Therefore, the sale by PRS to FC is a related party sale within the meaning of § 1.250(b)–6(b)(1). Under section 250(b)(5)(C)(i) and § 1.250(b)–6(c), because FC did not sell the property, or use the property in connection with other property sold or the provision of a service, to a foreign unrelated party before the property was subject to a domestic use, the sale by PRS to FC is not a FDDEI sale. See § 1.250(b)–6(c)(1). Accordingly, the gain from the sale ($20x) is included in PRS's gross DEI but not its gross FDDEI, and DC's share of PRS's gain ($5x) is included in DC's gross DEI but not gross FDDEI. This is the result notwithstanding that FC is not a related party of DC because FC and DC are not members of a modified affiliated group within the meaning of paragraph (c)(17) of this section.

(f) *Determination of FDII for consolidated groups.* A member of a consolidated group (as defined in § 1.1502–1(h)) determines its FDII under the rules provided in § 1.1502–50.

(g) *Determination of FDII for tax-exempt corporations.* The FDII of a corporation that is subject to the unrelated business income tax under section 511 is determined only by reference to that corporation's items of income, gain, deduction, or loss, and adjusted bases in property, that are taken into account in computing the corporation's unrelated business taxable income (as defined in section 512). For example, if a corporation that is subject to the unrelated business income tax under section 511 has tangible property used in the production of both unrelated business income and gross income that is not unrelated business income, only the portion of the basis of such property taken into account in computing the corporation's unrelated business taxable income is taken into account in determining the corporation's QBAI. Similarly, if a corporation that is subject to the unrelated business income tax under section 511 has tangible property that is used in both the production of gross DEI and the production of gross income that is not gross DEI, only the corporation's unrelated business income is taken into account in determining the corporation's dual use ratio with respect to such property under § 1.250(b)–2(d)(3).

§ 1.250(b)–2 Qualified business asset investment (QBAI).

(a) *Scope.* This section provides general rules for determining the qualified business asset investment of a domestic corporation for purposes of determining its deemed tangible income return under § 1.250(b)–1(c)(4). Paragraph (b) of this section defines qualified business asset investment (QBAI). Paragraph (c) of this section defines tangible property and specified tangible property. Paragraph (d) of this section provides rules for determining the portion of property that is specified tangible property when the property is used in the production of both gross DEI and gross income that is not gross DEI. Paragraph (e) of this section provides rules for determining the adjusted basis of specified tangible property. Paragraph (f) of this section provides rules for determining QBAI of a domestic corporation with a short taxable year. Paragraph (g) of this section provides rules for increasing the QBAI of a domestic corporation by reason of property owned through a partnership. Paragraph (h) of this section provides an anti-avoidance rule that disregards certain transfers when determining the QBAI of a domestic corporation.

(b) *Definition of qualified business asset investment.* The term *qualified business asset investment (QBAI)* means the average of a domestic corporation's aggregate adjusted bases as of the close of each quarter of the domestic corporation's taxable year in specified tangible property that is used in a trade or business of the domestic corporation and is of a type with respect to which a deduction is allowable under section 167. In the case of partially depreciable property, only the depreciable portion of the property is of a type with respect to which a deduction is allowable under section 167.

(c) *Specified tangible property*—(1) *In general.* The term *specified tangible property* means, with respect to a domestic corporation for a taxable year, tangible property of the domestic corporation used in the production of gross DEI for the taxable year. For purposes of the preceding sentence, tangible property of a domestic corporation is used in the production of gross DEI for a taxable year if some or all of the depreciation or cost recovery allowance with respect to the tangible property is either allocated and apportioned to the gross DEI of the domestic corporation for the taxable year under § 1.250(b)–1(d)(2) or capitalized to inventory or other property held for sale, some or all of the gross income or loss from the sale of which is taken into account in determining DEI of the domestic corporation for the taxable year.

(2) *Tangible property.* The term *tangible property* means property for which the depreciation deduction provided by section 167(a) is eligible to be determined under section 168 without regard to section 168(f)(1), (2), or (5), section 168(k)(2)(A)(i)(II), (IV), or (V), and the date placed in service.

(d) *Dual use property*—(1) *In general.* The amount of the adjusted basis in dual use property of a domestic corporation for a taxable year that is treated as adjusted basis in specified tangible property for the taxable year is

the average of the domestic corporation's adjusted basis in the property multiplied by the dual use ratio with respect to the property for the taxable year.

(2) *Definition of dual use property.* The term *dual use property* means, with respect to a domestic corporation and a taxable year, specified tangible property of the domestic corporation that is used in both the production of gross DEI and the production of gross income that is not gross DEI for the taxable year. For purposes of the preceding sentence, specified tangible property of a domestic corporation is used in the production of gross DEI and the production of gross income that is not gross DEI for a taxable year if less than all of the depreciation or cost recovery allowance with respect to the property is either allocated and apportioned to the gross DEI of the domestic corporation for the taxable year under § 1.250(b)–1(d)(2) or capitalized to inventory or other property held for sale, the gross income or loss from the sale of which is taken into account in determining the DEI of the domestic corporation for the taxable year.

(3) *Dual use ratio.* The term *dual use ratio* means, with respect to dual use property, a domestic corporation, and a taxable year, a ratio (expressed as a percentage) calculated as—

(i) The sum of—

(A) The depreciation deduction or cost recovery allowance with respect to the property that is allocated and apportioned to the gross DEI of the domestic corporation for the taxable year under § 1.250(b)–1(d)(2); and

(B) The depreciation or cost recovery allowance with respect to the property that is capitalized to inventory or other property held for sale, the gross income or loss from the sale of which is taken into account in determining the DEI of the domestic corporation for the taxable year; divided by

(ii) The sum of—

(A) The total amount of the domestic corporation's depreciation deduction or cost recovery allowance with respect to the property for the taxable year; and

(B) The total amount of the domestic corporation's depreciation or cost recovery allowance with respect to the property capitalized to inventory or other property held for sale, the gross income or loss from the sale of which is taken into account in determining the income or loss of the domestic corporation for the taxable year.

(4) *Example.* The following example illustrates the application of this paragraph (d).

(i) *Facts.* DC, a domestic corporation, owns a machine that produces both gross DEI and income that is not gross DEI. The average adjusted basis of the machine for the taxable year in the hands of DC is $4,000x. The depreciation with respect to the machine for the taxable year is $400x, $320x of which is capitalized to inventory of Product A, gross income or loss from the sale of which is taken into account in determining DC's gross DEI for the taxable year, and $80x of which is capitalized to inventory of Product B, gross income or loss from the sale of which is not taken into account in determining DC's gross DEI for the taxable year. DC also owns an office building for its administrative functions with an average adjusted basis for the taxable year of $10,000x. DC does not capitalize depreciation with respect to the office building to inventory or other property held for sale. DC's depreciation deduction with respect to the office building is $1,000x for the taxable year, $750x of which is allocated and apportioned to gross DEI under § 1.250(b)–1(d)(2), and $250x of which is allocated and apportioned to income other than gross DEI under § 1.250(b)–1(d)(2).

(ii) *Analysis*—(A) *Dual use property.* The machine and office building are property for which the depreciation deduction provided by section 167(a) is eligible to be determined under section 168 (without regard to section 168(f)(1), (2), or (5), section 168(k)(2)(A)(i)(II), (IV), or (V), and the date placed in service). Therefore, under paragraph (c)(2) of this section, the machine and office building are tangible property. Furthermore, because the machine and office building are used in the production of gross DEI for the taxable year within the meaning of paragraph (c)(1) of this section, the machine and office building are specified tangible property. Finally, because the machine and office building are used in both the production of gross DEI and the production of gross income that is not gross DEI for the taxable year within the meaning of paragraph (d)(2) of this section, the machine and office building are dual use property. Therefore, under paragraph (d)(1) of this section, the amount of DC's adjusted basis in the machine and office building that is treated as adjusted basis in specified tangible property for the taxable year is determined by multiplying DC's adjusted basis in the machine and office building by DC's dual use ratio with respect to the machine and office building determined under paragraph (d)(3) of this section.

(B) *Depreciation not capitalized to inventory.* Because none of the depreciation with respect to the office building is capitalized to inventory or other property held for sale, DC's dual use ratio with respect to the office building is determined entirely by reference to the depreciation deduction with respect to the office building. Therefore, under paragraph (d)(3) of this section, DC's dual use ratio with respect to the office building for Year 1 is 75 percent, which is DC's depreciation deduction with respect to the office building that is allocated and apportioned to gross DEI under § 1.250(b)–1(d)(2) for Year 1 ($750x), divided by the total amount of DC's depreciation deduction with respect to the office building for Year 1 ($1000x). Accordingly, under paragraph (d)(1) of this section, $7,500x ($10,000x × 0.75) of DC's average adjusted bases in the office building is taken into account under paragraph (b) of this section in determining DC's QBAI for the taxable year.

(C) *Depreciation capitalized to inventory.* Because all of the depreciation with respect to the machine is capitalized to inventory, DC's dual use ratio with respect to the machine is determined entirely by reference to the depreciation with respect to the machine that is capitalized to inventory and included in cost of goods sold. Therefore, under paragraph (d)(3) of this section, DC's dual use ratio with respect to the machine for the taxable year is 80 percent, which is DC's depreciation with respect to the machine that is capitalized to inventory of Product A, the gross income or loss from the sale of which is taken into account in determining in DC's DEI for the taxable year ($320x), divided by DC's depreciation with respect to the machine that is capitalized to inventory, the gross income or loss from the sale of which is taken into account in determining DC's income for Year 1 ($400x). Accordingly, under paragraph (d)(1) of this section, $3,200x ($4,000x × 0.8) of DC's average adjusted basis in the machine is taken into account under paragraph (b) of this section in determining DC's QBAI for the taxable year.

(e) *Determination of adjusted basis of specified tangible property*—(1) *In general.* The adjusted basis in specified tangible property for purposes of this section is determined by using the cost capitalization methods of accounting used by the domestic corporation for purposes of determining the gross income and deductions of the domestic corporation and the alternative depreciation system under section 168(g), and by allocating the depreciation deduction with respect to such property for the domestic corporation's taxable year ratably to each day during the period in the taxable year to which such depreciation relates. For purposes of the preceding sentence, the period in the taxable year to which such depreciation relates is determined without regard to the applicable convention under section 168(d).

(2) *Effect of change in law.* The adjusted basis in specified tangible property is determined without regard to any provision of law enacted after December 22, 2017, unless such later enacted law specifically and directly amends the definition of QBAI under section 250 or section 951A.

(3) *Specified tangible property placed in service before enactment of section 250.* The adjusted basis in specified tangible property placed in service before December 22, 2017, is determined using the alternative depreciation system under section 168(g), as if this system had applied from the date that the property was placed in service.

(f) *Special rules for short taxable years*—(1) *In general.* In the case of a domestic corporation that has a taxable year that is less than twelve months (a *short taxable year*), the rules for determining the QBAI of the domestic corporation under this section are modified as provided in paragraphs (f)(2) and (3) of this section with respect to the taxable year.

(2) *Determination of when the quarter closes.* For purposes of determining when the quarter closes, in determining the QBAI of a domestic corporation for a short taxable year, the quarters of the domestic corporation for purposes of this section are the full quarters beginning and ending within the short taxable year (if any), determining quarter length as if the domestic corporation did not have a short taxable year, plus one or more short quarters (if any).

(3) *Reduction of qualified business asset investment.* The QBAI of a domestic corporation for a short taxable year is the sum of—

(i) The sum of the domestic corporation's aggregate adjusted bases in specified tangible property as of the close of each full quarter (if any) in the domestic corporation's taxable year divided by four; plus

(ii) The domestic corporation's aggregate adjusted bases in specified tangible property as of the close of each short quarter (if any) in the domestic corporation's taxable year multiplied by the sum of the number of days in each short quarter divided by 365.

(4) *Example.* The following example illustrates the application of this paragraph (f).

(i) *Facts.* A, an individual, owns all of the stock of DC, a domestic corporation. A owns DC from the beginning of the taxable year. On July 15 of the taxable year, A sells DC to USP, a domestic corporation that is unrelated to A. DC becomes a member of the consolidated group of which USP is the common parent and as a result, under § 1.1502–76(b)(2)(ii), DC's taxable year is treated as ending on July 15. USP and DC both use the calendar year as their taxable year. DC's aggregate adjusted bases in specified tangible property for the taxable year are $250x as of March 31, $300x as of June 30, $275x as of July 15, $500x as of September 30, and $450x as of December 31.

(ii) *Analysis*—(A) *Determination of short taxable years and quarters.* DC has two short taxable years during the year. The first short taxable year is from January 1 to July 15, with two full quarters (January 1 through March 31 and April 1 through June 30) and one short quarter (July 1 through July 15). The second taxable year is from July 16 to December 31, with one short quarter (July 16 through September 30) and one full quarter (October 1 through December 31).

(B) *Calculation of qualified business asset investment for the first short taxable year.* Under paragraph (f)(2) of this section, for the first short taxable year, DC has three quarter closes (March 31, June 30, and July 15). Under paragraph (f)(3) of this section, the QBAI of DC for the first short taxable year is $148.80x, the sum of $137.50x (($250x + $300x)/4) attributable to the two full quarters and $11.30x ($275x × 15/365) attributable to the short quarter.

(C) *Calculation of qualified business asset investment for the second short taxable year.* Under paragraph (f)(2) of this section, for the second short taxable year, DC has two quarter closes (September 30 and December 31). Under paragraph (f)(3) of this section, the QBAI of DC for the second short taxable year is $217.98x, the sum of $112.50x ($450x/4) attributable to the one full quarter and $105.48x ($500x × 77/365) attributable to the short quarter.

(g) *Partnership property*—(1) *In general.* If a domestic corporation holds an interest in one or more partnerships during a taxable year (including indirectly through one or more partnerships that are partners in a lower-tier partnership), the QBAI of the domestic corporation for the taxable year (determined without regard to this paragraph (g)(1)) is increased by the sum of the domestic corporation's partnership QBAI with respect to each partnership for the taxable year.

(2) *Determination of partnership QBAI.* For purposes of paragraph (g)(1) of this section, the term *partnership QBAI* means, with respect to a partnership, a domestic corporation, and a taxable year, the sum of the domestic corporation's partner adjusted basis in each partnership specified tangible property of the partnership for each partnership taxable year that ends with or within the taxable year. If a partnership taxable year is less than twelve months, the principles of paragraph (f) of this section apply in determining a domestic corporation's partnership QBAI with respect to the partnership.

(3) *Determination of partner adjusted basis*—(i) *In general.* For purposes of paragraph (g)(2) of this section, the term *partner adjusted basis* means the amount described in paragraph (g)(3)(ii) of this section with respect to sole use partnership property or paragraph (g)(3)(iii) of this section with respect to dual use partnership property. The principles of section 706(d) apply to this determination.

(ii) *Sole use partnership property*—(A) *In general.* The amount described in this paragraph (g)(3)(ii), with respect to sole use partnership property, a partnership taxable year, and a domestic corporation, is the sum of the domestic corporation's proportionate share of the partnership adjusted basis in the sole use partnership property for the partnership taxable year and the domestic corporation's partner-specific QBAI basis in the sole use partnership property for the partnership taxable year.

(B) *Definition of sole use partnership property.* The term *sole use partnership property* means, with respect to a partnership, a partnership taxable year, and a domestic corporation, partnership specified tangible property of the partnership that is used in the production of only gross DEI of the domestic corporation for the taxable year in which or with which the partnership taxable year ends. For purposes of the preceding sentence, partnership specified tangible property of a partnership is used in the production of only gross DEI for a taxable year if all the domestic corporation's distributive share of the partnership's depreciation deduction or cost recovery allowance with respect to the property (if any) for the partnership taxable year that ends with or within the taxable year is allocated and apportioned to the domestic corporation's gross DEI for the taxable year under § 1.250(b)–1(d)(2) and, if any of the partnership's depreciation or cost recovery allowance with respect to the property is capitalized to inventory or other property held for sale, all the domestic corporation's distributive share of the partnership's gross income or loss from the sale of such inventory or other property for the partnership taxable year that ends with or within the taxable year is taken into account in determining the DEI of the domestic corporation for the taxable year.

(iii) *Dual use partnership property*—(A) *In general.* The amount described in this paragraph (g)(3)(iii), with respect to dual use partnership property, a partnership taxable year, and a domestic corporation, is the sum of the domestic corporation's proportionate share of the partnership adjusted basis in the property for the partnership taxable year and the domestic corporation's partner-specific QBAI basis in the property for the partnership taxable year, multiplied by the domestic corporation's dual use ratio with respect to the property for the partnership taxable year determined under the principles of paragraph (d)(3) of this section, except that the ratio described in paragraph (d)(3) of this section is determined by reference to the domestic corporation's distributive share of the amounts described in paragraph (d)(3) of this section.

(B) *Definition of dual use partnership property.* The term *dual use partnership property* means partnership specified tangible property other than sole use partnership property.

(4) *Determination of proportionate share of the partnership's adjusted basis in partnership specified tangible property*—(i) *In general.* For purposes of paragraph (g)(3) of this section, the domestic corporation's proportionate share of the partnership adjusted basis in partnership specified tangible property for a partnership taxable year is the partnership adjusted basis in the property multiplied by the domestic corporation's proportionate share ratio with respect to the property for the partnership taxable year. Solely for purposes of determining the proportionate share ratio under paragraph (g)(4)(ii) of this section, the partnership's calculation of, and a partner's distributive share of, any income, loss, depreciation, or cost recovery allowance is determined under section 704(b).

(ii) *Proportionate share ratio.* The term *proportionate share ratio* means, with respect to a partnership, a partnership taxable year, and a domestic corporation, the ratio (expressed as a percentage) calculated as—

(A) The sum of—

(*1*) The domestic corporation's distributive share of the partnership's depreciation deduction or cost recovery allowance with respect to the property for the partnership taxable year; and

(*2*) The amount of the partnership's depreciation or cost recovery allowance with respect to the property that is capitalized to inventory or other property held for sale, the gross income or loss from the sale of which is taken into account in determining the domestic corporation's distributive share of the partnership's income or loss for the partnership taxable year; divided by

(B) The sum of—

(*1*) The total amount of the partnership's depreciation deduction or cost recovery allowance with respect to the property for the partnership taxable year; and

(*2*) The total amount of the partnership's depreciation or cost recovery allowance with respect to the property capitalized to inventory or other property held for sale, the gross income or loss from the sale of which is taken into account in determining the partnership's income or loss for the partnership taxable year.

(5) *Definition of partnership specified tangible property.* The term *partnership specified tangible property* means, with respect to a domestic corporation, tangible property (as defined in paragraph (c)(2) of this section) of a partnership that is—

(i) Used in the trade or business of the partnership;

(ii) Of a type with respect to which a deduction is allowable under section 167; and

(iii) Used in the production of gross income included in the domestic corporation's gross DEI.

(6) *Determination of partnership adjusted basis.* For purposes of this paragraph (g), the term *partnership adjusted basis* means, with respect to a partnership, partnership specified tangible property, and a partnership taxable year, the amount equal to the average of the partnership's adjusted basis in the partnership specified tangible property as of the close of each quarter in the partnership taxable year determined without regard to any adjustments under section 734(b) except for adjustments under section 734(b)(1)(B) or section 734(b)(2)(B) that are attributable to distributions of tangible property (as defined in paragraph (c)(2) of this section) and for adjustments under section 734(b)(1)(A) or 734(b)(2)(A). The principles of paragraphs (e) and (h) of this section apply for purposes of determining a partnership's adjusted basis in partnership specified tangible property and the proportionate share of the partnership's adjusted basis in partnership specified tangible property.

(7) *Determination of partner-specific QBAI basis.* For purposes of this paragraph (g), the term *partner-specific QBAI basis* means, with respect to a domestic corporation, a partnership, and partnership specified tangible property, the amount that is equal to the average of the basis adjustment under section 743(b) that is allocated to the partnership specified tangible property of the partnership with respect to the domestic corporation as of the close of each quarter in the partnership taxable year. For this purpose, a negative basis adjustment under section 743(b) is expressed as a negative number. The principles of paragraphs (e) and (h) of this section apply for purposes of determining the partner-specific QBAI basis with respect to partnership specified tangible property.

(8) *Examples.* The following examples illustrate the rules of this paragraph (g).

(i) *Assumed facts.* Except as otherwise stated, the following facts are assumed for purposes of the examples:

(A) DC, DC1, DC2, and DC3 are domestic corporations.

(B) PRS is a partnership and its allocations satisfy the requirements of section 704.

(C) All properties are partnership specified tangible property.

(D) All persons use the calendar year as their taxable year.

(E) There is no partner-specific QBAI basis with respect to any property.

(ii) *Example 1: Sole use partnership property*—(A) *Facts.* DC is a partner in PRS. PRS owns two properties, Asset A and Asset B. The average of PRS's adjusted basis as of the close of each quarter of PRS's taxable year in Asset A is $100x and in Asset B is $500x. In Year 1, PRS's section 704(b) depreciation deduction is $10x with respect to Asset A and $5x with respect to Asset B, and DC's section 704(b) distributive share of the depreciation deduction is $8x with respect to Asset A and $1x with respect to Asset B. None of the depreciation with respect to Asset A or Asset B is capitalized to inventory or other property held for sale. DC's entire distributive share of the depreciation deduction with respect to Asset A and Asset B is allocated and apportioned to DC's gross DEI for Year 1 under § 1.250(b)–1(d)(2).

(B) *Analysis*—(*1*) *Sole use partnership property.* Because all of DC's distributive share of the depreciation deduction with respect to Asset A and B is allocated and apportioned to gross DEI for Year 1, Asset A and Asset B are sole use partnership property within the meaning of paragraph (g)(3)(ii)(B) of this section. Therefore, under paragraph (g)(3)(ii)(A) of this section, DC's partner adjusted basis in Asset A and Asset B is equal to the sum of DC's proportionate share of PRS's partnership adjusted basis in Asset A and Asset B for Year 1 and DC's partner-specific QBAI basis in Asset A and Asset B for Year 1, respectively.

(*2*) *Proportionate share.* Under paragraph (g)(4)(i) of this section, DC's proportionate share of PRS's partnership adjusted basis in Asset A and Asset B is PRS's partnership adjusted basis in Asset A and Asset B for Year 1, multiplied by DC's proportionate share ratio with respect to Asset A and Asset B for Year 1, respectively. Because none of the depreciation with respect to Asset A or Asset B is capitalized to inventory or other property held for sale, DC's proportionate share ratio with respect to Asset A and Asset B is determined entirely by reference to the depreciation deduction with respect to Asset A and Asset B. Therefore, DC's proportionate share ratio with respect to Asset A for Year 1 is 80 percent, which is the ratio of DC's section 704(b) distributive share of PRS's section 704(b) depreciation deduction with respect to Asset A for Year 1 ($8x), divided by the total amount of PRS's section 704(b) depreciation deduction with respect to Asset A for Year 1 ($10x). DC's proportionate share ratio with respect to Asset B for Year 1 is 20 percent, which is the ratio of DC's section 704(b) distributive share of PRS's section 704(b) depreciation deduction with respect to Asset B for Year 1 ($1x), divided by the total amount of PRS's section 704(b) depreciation deduction with respect to Asset B for Year 1 ($5x). Accordingly, under paragraph (g)(4)(i) of this section, DC's proportionate share of PRS's partnership adjusted basis in Asset A is $80x ($100x × 0.8), and DC's proportionate share of PRS's partnership adjusted basis in Asset B is $100x ($500x × 0.2).

(*3*) *Partner adjusted basis.* Because DC has no partner-specific QBAI basis with respect to Asset A and Asset B, DC's partner adjusted basis in Asset A and Asset B is determined

entirely by reference to its proportionate share of PRS's partnership adjusted basis in Asset A and Asset B. Therefore, under paragraph (g)(3)(ii)(A) of this section, DC's partner adjusted basis in Asset A is $80x, DC's proportionate share of PRS's partnership adjusted basis in Asset A, and DC's partner adjusted basis in Asset B is $100x, DC's proportionate share of PRS's partnership adjusted basis in Asset B.

(*4*) *Partnership QBAI.* Under paragraph (g)(2) of this section, DC's partnership QBAI with respect to PRS is $180x, the sum of DC's partner adjusted basis in Asset A ($80x) and DC's partner adjusted basis in Asset B ($100x). Accordingly, under paragraph (g)(1) of this section, DC increases its QBAI for Year 1 by $180x.

(iii) *Example 2: Dual use partnership property*—(A) *Facts.* DC owns a 50 percent interest in PRS. All section 704(b) and tax items are identical and are allocated equally between DC and its other partner. PRS owns three properties, Asset C, Asset D, and Asset E. PRS sells two products, Product A and Product B. All of DC's distributive share of the gross income or loss from the sale of Product A is taken into account in determining DC's DEI, and none of DC's distributive share of the gross income or loss from the sale of Product B is taken into account in determining DC's DEI.

(*1*) *Asset C.* The average of PRS's adjusted basis as of the close of each quarter of PRS's taxable year in Asset C is $100x. In Year 1, PRS's depreciation is $10x with respect to Asset C, none of which is capitalized to inventory or other property held for sale. DC's distributive share of the depreciation deduction with respect to Asset C is $5x ($10x × 0.5), $3x of which is allocated and apportioned to DC's gross DEI under § 1.250(b)–1(d)(2).

(*2*) *Asset D.* The average of PRS's adjusted basis as of the close of each quarter of PRS's taxable year in Asset D is $500x. In Year 1, PRS's depreciation is $50x with respect to Asset D, $10x of which is capitalized to inventory of Product A and $40x is capitalized to inventory of Product B. None of the $10x depreciation with respect to Asset D capitalized to inventory of Product A is capitalized to ending inventory. However, of the $40x capitalized to inventory of Product B, $10x is capitalized to ending inventory. Therefore, the amount of depreciation with respect to Asset D capitalized to inventory of Product A that is taken into account in determining DC's distributive share of the income or loss of PRS for Year 1 is $5x ($10x × 0.5), and the amount of depreciation with respect to Asset D capitalized to inventory of Product B that is taken into account in determining DC's distributive share of the income or loss of PRS for Year 1 is $15x ($30x × 0.5).

(*3*) *Asset E.* The average of PRS's adjusted basis as of the close of each quarter of PRS's taxable year in Asset E is $600x. In Year 1, PRS's depreciation is $60x with respect to Asset E. Of the $60x depreciation with respect to Asset E, $20x is allowed as a deduction, $24x is capitalized to inventory of Product A, and $16x is capitalized to inventory of Product B. DC's distributive share of the depreciation deduction with respect to Asset E is $10x ($20x × 0.5), $8x of which is allocated and apportioned to DC's gross DEI under § 1.250(b)–1(d)(2). None of the $24x depreciation with respect to Asset E capitalized to inventory of Product A is capitalized to ending inventory. However, of the $16x depreciation with respect to Asset E capitalized to inventory of Product B, $10x is capitalized to ending inventory. Therefore, the amount of depreciation with respect to Asset E capitalized to inventory of Product A that is taken into account in determining DC's distributive share of the income or loss of PRS for Year 1 is $12x ($24x × 0.5), and the amount of depreciation with respect to Asset E capitalized to inventory of Product B that is taken into account in determining DC's distributive share of the income or loss of PRS for Year 1 is $3x ($6x × 0.5).

(B) *Analysis.* Because Asset C, Asset D, and Asset E are not used in the production of only gross DEI in Year 1 within the meaning of paragraph (g)(3)(ii)(B) of this section, Asset C, Asset D, and Asset E are dual use partnership property within the meaning of paragraph (g)(3)(iii)(B) of this section. Therefore, under paragraph (g)(3)(iii)(A) of this section, DC's partner adjusted basis in Asset C, Asset D, and Asset E is the sum of DC's proportionate share of PRS's partnership adjusted basis in Asset C, Asset D, and Asset E, respectively, for Year 1, and DC's partner-specific QBAI basis in Asset C, Asset D, and Asset E, respectively, for Year 1, multiplied by DC's dual use ratio with respect to Asset C, Asset D, and Asset E, respectively, for Year 1, determined under the principles of paragraph (d)(3) of this section, except that the ratio described in paragraph (d)(3) of this section is determined by reference to DC's distributive share of the amounts described in paragraph (d)(3) of this section.

(*1*) *Asset C*—(*i*) *Proportionate share.* Under paragraph (g)(4)(i) of this section, DC's proportionate share of PRS's partnership adjusted basis in Asset C is PRS's partnership adjusted basis in Asset C for Year 1, multiplied by DC's proportionate share ratio with respect to Asset C for Year 1. Because none of the depreciation with respect to Asset C is capitalized to inventory or other property held for sale, DC's proportionate share ratio with respect to Asset C is determined entirely by reference to the depreciation deduction with respect to Asset C. Therefore, DC's proportionate share ratio with respect to Asset C is 50 percent, which is the ratio calculated as the amount of DC's section 704(b) distributive share of PRS's section 704(b) depreciation deduction with respect to Asset C for Year 1 ($5x), divided by the total amount of PRS's section 704(b) depreciation deduction with respect to Asset C for Year 1 ($10x). Accordingly, under paragraph (g)(4)(i) of this section, DC's proportionate share of PRS's partnership adjusted basis in Asset C is $50x ($100x × 0.5).

(*ii*) *Dual use ratio.* Because none of the depreciation with respect to Asset C is capitalized to inventory or other property held for sale, DC's dual use ratio with respect to Asset C is determined entirely by reference to the depreciation deduction with respect to Asset C. Therefore, DC's dual use ratio with respect to Asset C is 60 percent, which is the ratio calculated as the amount of DC's distributive share of PRS's depreciation deduction with respect to Asset C that is allocated and apportioned to DC's gross DEI under § 1.250(b)–1(d)(2) for Year 1 ($3x), divided by the total amount of DC's distributive share of PRS's depreciation deduction with respect to Asset C for Year 1 ($5x).

(*iii*) *Partner adjusted basis.* Because DC has no partner-specific QBAI basis with respect to Asset C, DC's partner adjusted basis in Asset C is determined entirely by reference to DC's proportionate share of PRS's partnership adjusted basis in Asset C, multiplied by DC's dual use ratio with respect to Asset C. Under paragraph (g)(3)(iii)(A) of this section, DC's partner adjusted basis in Asset C is $30x, DC's proportionate share of PRS's partnership adjusted basis in Asset C for Year 1 ($50x), multiplied by DC's dual use ratio with respect to Asset C for Year 1 (60 percent).

(*2*) *Asset D*—(*i*) *Proportionate share.* Under paragraph (g)(4)(i) of this section, DC's proportionate share of PRS's partnership adjusted basis in Asset D is PRS's partnership adjusted basis in Asset D for Year 1, multiplied by DC's proportionate share ratio with respect to Asset D for Year 1. Because all of the depreciation with respect to Asset D is capitalized to inventory, DC's proportionate share ratio with respect to Asset D is determined entirely by reference to the depreciation with respect to Asset D that is capitalized to inventory and included in cost of goods sold. Therefore, DC's proportionate share ratio with respect to Asset D is 50 percent, which is the ratio calculated as the amount of PRS's section 704(b) depreciation with respect to Asset D capitalized to Product A and Product B that is taken into account in determining DC's section 704(b) distributive share of PRS's income or loss for Year 1 ($20x), divided by the total amount of PRS's section 704(b) depreciation with respect to Asset D capitalized to Product A and Product B that is taken into account in determining PRS's section 704(b) income or loss for Year 1 ($40x). Accordingly, under paragraph (g)(4)(i) of this section, DC's proportionate share of PRS's partnership adjusted basis in Asset D is $250x ($500x × 0.5).

(*ii*) *Dual use ratio.* Because all of the depreciation with respect to Asset D is capitalized to inventory, DC's dual use ratio with respect to Asset D is determined entirely by reference to the depreciation with respect to Asset D that is capitalized to inventory and included in cost of goods sold. Therefore, DC's dual use ratio with respect to Asset D is 25 percent, which is the ratio calculated as the amount of depreciation with respect to Asset D capitalized to inventory of Product A and Product B that is taken into account in determining DC's DEI for Year 1 ($5x), divided by the total amount of depreciation with respect to Asset D capitalized to inventory of Product A and Product B that is taken into account in determining DC's income or loss for Year 1 ($20x).

(*iii*) *Partner adjusted basis.* Because DC has no partner-specific QBAI basis with respect

to Asset D, DC's partner adjusted basis in Asset D is determined entirely by reference to DC's proportionate share of PRS's partnership adjusted basis in Asset D, multiplied by DC's dual use ratio with respect to Asset D. Under paragraph (g)(3)(iii)(A) of this section, DC's partner adjusted basis in Asset D is $62.50x, DC's proportionate share of PRS's partnership adjusted basis in Asset D for Year 1 ($250x), multiplied by DC's dual use ratio with respect to Asset D for Year 1 (25 percent).

(*3*) *Asset E*—(*i*) *Proportionate share.* Under paragraph (g)(4)(i) of this section, DC's proportionate share of PRS's partnership adjusted basis in Asset E is PRS's partnership adjusted basis in Asset E for Year 1, multiplied by DC's proportionate share ratio with respect to Asset E for Year 1. Because the depreciation with respect to Asset E is partly deducted and partly capitalized to inventory, DC's proportionate share ratio with respect to Asset E is determined by reference to both the depreciation that is deducted and the depreciation that is capitalized to inventory and included in cost of goods sold. Therefore, DC's proportionate share ratio with respect to Asset E is 50 percent, which is the ratio calculated as the sum ($25x) of the amount of DC's section 704(b) distributive share of PRS's section 704(b) depreciation deduction with respect to Asset E for Year 1 ($10x) and the amount of PRS's section 704(b) depreciation with respect to Asset E capitalized to inventory of Product A and Product B that is taken into account in determining DC's section 704(b) distributive share of PRS's income or loss for Year 1 ($15x), divided by the sum ($50x) of the total amount of PRS's section 704(b) depreciation deduction with respect to Asset E for Year 1 ($20x) and the total amount of PRS's section 704(b) depreciation with respect to Asset E capitalized to inventory of Product A and Product B that is taken into account in determining PRS's section 704(b) income or loss for Year 1 ($30x). Accordingly, under paragraph (g)(4)(i) of this section, DC's proportionate share of PRS's partnership adjusted basis in Asset E is $300x ($600x × 0.5).

(*ii*) *Dual use ratio.* Because the depreciation with respect to Asset E is partly deducted and partly capitalized to inventory, DC's dual use ratio with respect to Asset E is determined by reference to the depreciation that is deducted and the depreciation that is capitalized to inventory and included in cost of goods sold. Therefore, DC's dual use ratio with respect to Asset E is 80 percent, which is the ratio calculated as the sum ($20x) of the amount of DC's distributive share of PRS's depreciation deduction with respect to Asset E that is allocated and apportioned to DC's gross DEI under § 1.250(b)–1(d)(2) for Year 1 ($8x) and the amount of depreciation with respect to Asset E capitalized to inventory of Product A and Product B that is taken into account in determining DC's DEI for Year 1 ($12x), divided by the sum ($25x) of the total amount of DC's distributive share of PRS's depreciation deduction with respect to Asset E for Year 1 ($10x) and the total amount of depreciation with respect to Asset E capitalized to inventory of Product A and Product B that is taken into account in determining DC's income or loss for Year 1 ($15x).

(*iii*) *Partner adjusted basis.* Because DC has no partner-specific QBAI basis with respect to Asset E, DC's partner adjusted basis in Asset E is determined entirely by reference to DC's proportionate share of PRS's partnership adjusted basis in Asset E, multiplied by DC's dual use ratio with respect to Asset E. Under paragraph (g)(3)(iii)(A) of this section, DC's partner adjusted basis in Asset E is $240x, DC's proportionate share of PRS's partnership adjusted basis in Asset E for Year 1 ($300x), multiplied by DC's dual use ratio with respect to Asset E for Year 1 (80 percent).

(*4*) *Partnership QBAI.* Under paragraph (g)(2) of this section, DC's partnership QBAI with respect to PRS is $332.50x, the sum of DC's partner adjusted basis in Asset C ($30x), DC's partner adjusted basis in Asset D ($62.50x), and DC's partner adjusted basis in Asset E ($240x). Accordingly, under paragraph (g)(1) of this section, DC increases its QBAI for Year 1 by $332.50x.

(iv) *Example 3: Sole use partnership specified tangible property; section 743(b) adjustments*—(A) *Facts.* The facts are the same as in paragraph (g)(8)(ii)(A) of this section (the facts in *Example 1*), except that there is an average of $40x positive adjustment to the adjusted basis in Asset A as of the close of each quarter of PRS's taxable year with respect to DC under section 743(b) and an average of $20x negative adjustment to the adjusted basis in Asset B as of the close of each quarter of PRS's taxable year with respect to DC under section 743(b).

(B) *Analysis.* Under paragraph (g)(3)(ii)(A) of this section, DC's partner adjusted basis in Asset A is $120x, which is the sum of $80x (DC's proportionate share of PRS's partnership adjusted basis in Asset A as illustrated in paragraph (g)(8)(ii)(B)(*2*) of this section (the analysis in *Example 1*)) and $40x (DC's partner-specific QBAI basis in Asset A). Under paragraph (g)(3)(ii)(A) of this section, DC's partner adjusted basis in Asset B is $80x, the sum of $100x (DC's proportionate share of the partnership adjusted basis in the property as illustrated in paragraph (g)(8)(ii)(B)(*2*) of this section (the analysis in *Example 1*)) and (−$20x) (DC's partner-specific QBAI basis in Asset B). Therefore, under paragraph (g)(2) of this section, DC's partnership QBAI with respect to PRS is $200x ($120x + $80x). Accordingly, under paragraph (g)(1) of this section, DC increases its QBAI for Year 1 by $200x.

(v) *Example 4: Sale of partnership interest before close of taxable year*—(A) *Facts.* DC1 owns a 50 percent interest in PRS on January 1 of Year 1. PRS does not have an election under section 754 in effect. On July 1 of Year 1, DC1 sells its entire interest in PRS to DC2. PRS owns Asset G. The average of PRS's adjusted basis as of the close of each quarter of PRS's taxable year in Asset G is $100x. DC1's section 704(b) distributive share of the depreciation deduction with respect to Asset G is 25 percent with respect to PRS's entire year. DC2's section 704(b) distributive share of the depreciation deduction with respect to Asset G is also 25 percent with respect to PRS's entire year. Both DC1's and DC2's entire distributive shares of the depreciation deduction with respect to Asset G are allocated and apportioned under § 1.250(b)–1(d)(2) to DC1's and DC2's gross DEI, respectively, for Year 1. PRS's allocations satisfy section 706(d).

(B) *Analysis*—(*1*) *DC1.* Because DC1 owns an interest in PRS during DC1's taxable year and receives a distributive share of partnership items of the partnership under section 706(d), DC1 has partnership QBAI with respect to PRS in the amount determined under paragraph (g)(2) of this section. Under paragraph (g)(3)(i) of this section, DC1's partner adjusted basis in Asset G is $25x, the product of $100x (the partnership's adjusted basis in the property) and 25 percent (DC1's section 704(b) distributive share of depreciation deduction with respect to Asset G). Therefore, DC1's partnership QBAI with respect to PRS is $25x. Accordingly, under paragraph (g)(1) of this section, DC1 increases its QBAI by $25x for Year 1.

(*2*) *DC2.* DC2's partner adjusted basis in Asset G is also $25x, the product of $100x (the partnership's adjusted basis in the property) and 25 percent (DC2's section 704(b) distributive share of depreciation deduction with respect to Asset G). Therefore, DC2's partnership QBAI with respect to PRS is $25x. Accordingly, under paragraph (g)(1) of this section, DC2 increases its QBAI by $25x for Year 1.

(vi) *Example 5: Partnership adjusted basis; distribution of property in liquidation of partnership interest*—(A) *Facts.* DC1, DC2, and DC3 are equal partners in PRS, a partnership. DC1 and DC2 each has an adjusted basis of $100x in its partnership interest. DC3 has an adjusted basis of $50x in its partnership interest. PRS has a section 754 election in effect. PRS owns Asset H with a fair market value of $50x and an adjusted basis of $0, Asset I with a fair market value of $100x and an adjusted basis of $100x, and Asset J with a fair market value of $150x and an adjusted basis of $150x. Asset H and Asset J are tangible property, but Asset I is not tangible property. PRS distributes Asset I to DC3 in liquidation of DC3's interest in PRS. None of DC1, DC2, DC3, or PRS recognizes gain on the distribution. Under section 732(b), DC3's adjusted basis in Asset I is $50x. PRS's adjusted basis in Asset H is increased by $50x to $50x under section 734(b)(1)(B), which is the amount by which PRS's adjusted basis in Asset I immediately before the distribution exceeds DC3's adjusted basis in Asset I.

(B) *Analysis.* Under paragraph (g)(6) of this section, PRS's adjusted basis in Asset H is determined without regard to any adjustments under section 734(b) except for adjustments under section 734(b)(1)(B) or section 734(b)(2)(B) that are attributable to distributions of tangible property and for adjustments under section 734(b)(1)(A) or 734(b)(2)(A). The adjustment to the adjusted basis in Asset H is under section 734(b)(1)(B) and is attributable to the distribution of Asset I, which is not tangible property. Accordingly, for purposes of applying paragraph (g)(1) of this section, PRS's adjusted basis in Asset H is $0.

(h) *Anti-avoidance rule for certain transfers of property*—(1) *In general.* If, with a principal purpose of decreasing the amount of its deemed tangible income return, a domestic corporation transfers specified tangible property (*transferred property*) to a specified related party of the domestic corporation and, within the disqualified period, the domestic corporation or an FDII-eligible related party of the domestic corporation leases the same or substantially similar property from any specified related party, then, solely for purposes of determining the QBAI of the domestic corporation under paragraph (b) of this section, the domestic corporation is treated as owning the transferred property from the later of the beginning of the term of the lease or date of the transfer of the property until the earlier of the end of the term of the lease or the end of the recovery period of the property.

(2) *Rule for structured arrangements.* For purposes of paragraph (h)(1) of this section, a transfer of specified tangible property to a person that is not a related party or lease of property from a person that is not a related party is treated as a transfer to or lease from a specified related party if the transfer or lease is pursuant to a structured arrangement. A structured arrangement exists only if either paragraph (h)(2)(i) or (ii) of this section is satisfied.

(i) The reduction in the domestic corporation's deemed tangible income return is priced into the terms of the arrangement with the transferee.

(ii) Based on all the facts and circumstances, the reduction in the domestic corporation's deemed tangible income return is a principal purpose of the arrangement. Facts and circumstances that indicate the reduction in the domestic corporation's deemed tangible income return is a principal purpose of the arrangement include—

(A) Marketing the arrangement as tax-advantaged where some or all of the tax advantage derives from the reduction in the domestic corporation's deemed tangible income return;

(B) Primarily marketing the arrangement to domestic corporations which earn FDDEI;

(C) Features that alter the terms of the arrangement, including the return, in the event the reduction in the domestic corporation's deemed tangible income return is no longer relevant; or

(D) A below-market return absent the tax effects or benefits resulting from the reduction in the domestic corporation's deemed tangible income return.

(3) *Per se rules for certain transactions.* For purposes of paragraph (h)(1) of this section, a transfer of property by a domestic corporation to a specified related party (including a party deemed to be a specified related party under paragraph (h)(2) of this section) followed by a lease of the same or substantially similar property by the domestic corporation or an FDII-eligible related party from a specified related party (including a party deemed to be a specified related party under paragraph (h)(2) of this section) is treated per se as occurring pursuant to a principal purpose of decreasing the amount of the domestic corporation's deemed tangible income return if both the transfer and the lease occur within a six-month period.

(4) *Definitions related to anti-avoidance rule.* The following definitions apply for purpose of this paragraph (h).

(i) *Disqualified period.* The term *disqualified period* means, with respect to a transfer, the period beginning one year before the date of the transfer and ending the earlier of the end of the remaining recovery period (under the system described in section 951A(d)(3)(A)) of the property or one year after the date of the transfer.

(ii) *FDII-eligible related party.* The term *FDII-eligible related party* means, with respect to a domestic corporation, a member of the same consolidated group as the domestic corporation or a partnership with respect to which at least 80 percent of the interests in partnership capital and profits are owned, directly or indirectly, by the domestic corporation or one or more members of the consolidated group that includes the domestic corporation.

(iii) *Specified related party.* The term *specified related party* means, with respect to a domestic corporation, a related party other than an FDII-eligible related party.

(iv) *Transfer.* The term *transfer* means any disposition, exchange, contribution, or distribution of property, and includes an indirect transfer. For example, a transfer of an interest in a partnership is treated as a transfer of the assets of the partnership. In addition, if paragraph (h)(1) of this section applies to treat a domestic corporation as owning specified tangible property by reason of a lease of property, the termination or lapse of the lease of the property is treated as a transfer of the specified tangible property by the domestic corporation to the lessor.

(5) *Transactions occurring before March 4, 2019.* Paragraph (h)(1) of this section does not apply to a transfer of property that occurs before March 4, 2019.

(6) *Examples.* The following examples illustrate the application of this paragraph (h).

(i) *Example 1: Sale-leaseback with a related party*—(A) *Facts.* DC, a domestic corporation, owns Asset A, which is specified tangible property. DC also owns all the single class of stock of DS, a domestic corporation, and FS1 and FS2, each a controlled foreign corporation. DC and DS are members of the same consolidated group. On January 1, Year 1, DC sells Asset A to FS1. At the time of the sale, Asset A had a remaining recovery period of 10 years under the alternative depreciation system. On February 1, Year 1, FS2 leases Asset B, which is substantially similar to Asset A, to DS for a five-year term ending on January 31, Year 6.

(B) *Analysis.* Because DC transfers specified tangible property (Asset A), to a specified related party of DC (FS1), and, within a six month period (January 1, Year 1 to February 1, Year 1), an FDII-eligible related party of DC (DS) leases a substantially similar property (Asset B) from a specified related party (FS2), DC's transfer of Asset A and lease of Asset B are treated as per se occurring pursuant to a principal purpose of decreasing the amount of its deemed tangible income return. Accordingly, for purposes of determining DC's QBAI, DC is treated as owning Asset A from February 1, Year 1, the later of the date of the transfer of Asset A (January 1, Year 1) and the beginning of the term of the lease of Asset B (February 1, Year 1), until January 31, Year 6, the earlier of the end of the term of the lease of Asset B (January 31, Year 6) or the remaining recovery period of Asset A (December 31, Year 10).

(ii) *Example 2: Sale-leaseback with a related party; lapse of initial lease*—(A) *Facts.* The facts are the same as in paragraph (h)(6)(i)(A) of this section (the facts in *Example 1*). In addition, DS allows the lease of Asset B to expire on February 1, Year 6. On June 1, Year 6, DS and FS2 renew the lease for a five-year term ending on May 31, Year 11.

(B) *Analysis.* Because DC is treated as owning Asset A under paragraph (h)(1) of this section, the lapse of the lease of Asset B is treated as a transfer of Asset A to FS2 on February 1, Year 6, under paragraph (h)(4)(iv) of this section. Further, because DC is deemed to transfer specified tangible property (Asset A) to a specified related party (FS2) upon the lapse of the lease, and within a six month period (February 1, Year 6 to June 1, Year 6), an FDII-eligible related party of DC (DS) leases a substantially similar property (Asset B), DC's deemed transfer of Asset A under paragraph (h)(4)(iv) of this section and lease of Asset B are treated as per se occurring pursuant to a principal purpose of decreasing the amount of its deemed tangible income return. Accordingly, for purposes of determining DC's QBAI, DC is treated as owning Asset A from June 1, Year 6, the later of the date of the deemed transfer of Asset A (February 1, Year 6) and the beginning of the term of the lease of Asset B (June 1, Year 6), until December 31, Year 10, the earlier of the end of the term of the lease

of Asset B (May 31, Year 11) or the remaining recovery period of Asset A (December 31, Year 10).

§ 1.250(b)–3 Foreign-derived deduction eligible income (FDDEI) transactions.

(a) *Scope.* This section provides rules related to the determination of whether a sale of property or provision of a service is a FDDEI transaction. Paragraph (b) of this section provides definitions related to the determination of whether a sale of property or provision of a service is a FDDEI transaction. Paragraph (c) of this section provides rules regarding a sale of property or provision of a service to a foreign government or an agency or instrumentality thereof. Paragraph (d) of this section provides a rule for characterizing a transaction with both sales and services elements. Paragraph (e) of this section provides a rule for determining whether a sale of property or provision of a service to a partnership is a FDDEI transaction. Paragraph (f) of this section provides rules for substantiating certain FDDEI transactions.

(b) *Definitions.* This paragraph (b) provides definitions that apply for purposes of this section and §§ 1.250(b)–4 through 1.250(b)–6.

(1) *Digital content.* The term *digital content* means a computer program or any other content in digital format. For example, digital content includes books in digital format, movies in digital format, and music in digital format. For purposes of this section, a computer program is a set of statements or instructions to be used directly or indirectly in a computer or other electronic device in order to bring about a certain result, and includes any media, user manuals, documentation, data base, or similar item if the media, user manuals, documentation, data base, or other similar item is incidental to the operation of the computer program.

(2) *End user.* Except as modified by § 1.250(b)–4(d)(2)(ii), the term *end user* means the person that ultimately uses or consumes property or a person that acquires property in a foreign retail sale. A person that acquires property for resale or otherwise as an intermediary is not an end user.

(3) *FDII filing date.* The term *FDII filing date* means, with respect to a sale of property by a seller or provision of a service by a renderer, the date, including extensions, by which the seller or renderer is required to file an income tax return (or in the case of a seller or renderer that is a partnership, a return of partnership income) for the taxable year in which the gross income from the sale of property or provision of a service is included in the gross income of the seller or renderer.

(4) *Finished goods.* The term *finished goods* means general property that is acquired by an end user.

(5) *Foreign person.* The term *foreign person* means a person (as defined in section 7701(a)(1)) that is not a United States person and includes a foreign government or an international organization.

(6) *Foreign related party.* The term *foreign related party* means, with respect to a seller or renderer, any foreign person that is a related party of the seller or renderer.

(7) *Foreign retail sale.* The term *foreign retail sale* means a sale of general property to a recipient that acquires the general property at a physical retail location (such as a store or warehouse) outside the United States.

(8) *Foreign unrelated party.* The term *foreign unrelated party* means, with respect to a seller, a foreign person that is not a related party of the seller.

(9) *Fungible mass of general property.* The term *fungible mass of general property* means multiple units of property for sale with similar or identical characteristics for which the seller does not know the specific identity of the recipient or the end user for a particular unit.

(10) *General property.* The term *general property* means any property other than: Intangible property (as defined in paragraph (b)(11) of this section); a security (as defined in section 475(c)(2)); an interest in a partnership, trust, or estate; a commodity described in section 475(e)(2)(A) that is not a physical commodity; or a commodity described in section 475(e)(2)(B) through (D). A physical commodity described in section 475(e)(2)(A) is treated as general property, including if it is sold pursuant to a forward or option contract (including a contract described in section 475(e)(2)(C), but not a section 1256 contract as defined in section 1256(b) or other similar contract that is traded on a U.S. or non-U.S. regulated exchange and cleared by a central clearing organization in a manner similar to a section 1256 contract) that is physically settled by delivery of the commodity (provided that the taxpayer physically settled the contract pursuant to a consistent practice adopted for business purposes of determining whether to cash or physically settle such contracts under similar circumstances).

(11) *Intangible property.* The term *intangible property* has the meaning set forth in section 367(d)(4). For purposes of section 250, intangible property does not include a copyrighted article as defined in § 1.861–18(c)(3).

(12) *International transportation property.* The term *international transportation property* means aircraft, railroad rolling stock, vessel, motor vehicle, or similar property that provides a mode of transportation and is capable of traveling internationally.

(13) *IP address.* The term *IP address* means a device's internet Protocol address.

(14) *Recipient.* The term *recipient* means a person that purchases property or services from a seller or renderer.

(15) *Renderer.* The term *renderer* means a person that provides a service to a recipient.

(16) *Sale.* The term *sale* means any sale, lease, license, sublicense, exchange, or other disposition of property, and includes any transfer of property in which gain or income is recognized under section 367. In addition, the term *sell* (and any form of the word sell) means any transfer by sale.

(17) *Seller.* The term *seller* means a person that sells property to a recipient.

(18) *United States.* The term *United States* has the meaning set forth in section 7701(a)(9), as expanded by section 638(1) with respect to mines, oil and gas wells, and other natural deposits.

(19) *United States person.* The term *United States person* has the meaning set forth in section 7701(a)(30), except that the term does not include an individual that is a bona fide resident of a United States territory within the meaning of section 937(a).

(20) *United States territory.* The term *United States territory* means American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands.

(c) *Foreign military sales and services.* If a sale of property or a provision of a service is made to the United States or an instrumentality thereof pursuant to 22 U.S.C. 2751 *et seq.* under which the United States or an instrumentality thereof purchases the property or service for resale or on-service to a foreign government or agency or instrumentality thereof, then the sale of property or provision of a service is treated as a FDDEI sale or FDDEI service without regard to § 1.250(b)–4 or § 1.250(b)–5.

(d) *Transactions with multiple elements.* A transaction is classified according to its overall predominant character for purposes of determining whether the transaction is a FDDEI sale under § 1.250(b)–4 or a FDDEI service under § 1.250(b)–5. For example, whether a transaction that includes both

a sales component and a service component is subject to § 1.250(b)–4 or § 1.250(b)–5 is determined based on whether the overall predominant character, taking into account all relevant facts and circumstances, is a sale or service. In addition, whether a transaction that includes both a sale of general property and a sale of intangible property is subject to § 1.250(b)–4(d)(1) or § 1.250(b)–4(d)(2) is determined based on whether the overall predominant character, taking into account all relevant facts and circumstances, is a sale of general property or a sale of intangible property.

(e) *Treatment of partnerships*—(1) *In general.* For purposes of determining whether a sale of property to or by a partnership or a provision of a service to or by a partnership is a FDDEI transaction, a partnership is treated as a person. Accordingly, for example, a partnership may be a seller, renderer, recipient, or related party, including a foreign related party (as defined in paragraph (b)(6) of this section).

(2) *Examples.* The following examples illustrate the application of this paragraph (e).

(i) *Example 1: Domestic partner sale to foreign partnership with a foreign branch*—(A) *Facts.* DC, a domestic corporation, is a partner in PRS, a foreign partnership. DC and PRS are not related parties. PRS has a foreign branch within the meaning of § 1.904–4(f)(3)(iii). DC and PRS both use the calendar year as their taxable year. For the taxable year, DC recognizes $20x of gain on the sale of general property to PRS for a foreign use (as determined under § 1.250(b)–4(d)). During the same taxable year, PRS recognizes $20x of gain on the sale of other general property to a foreign person for a foreign use (as determined under § 1.250(b)–4(d)). PRS's income on the sale of the property is attributable to its foreign branch.

(B) *Analysis.* DC's sale of property to PRS, a foreign partnership, is a FDDEI sale because it is a sale to a foreign person for a foreign use. Therefore, DC's gain of $20x on the sale to PRS is included in DC's gross DEI and gross FDDEI. However, PRS's gain of $20x is not included in the gross DEI or gross FDDEI of PRS because the gain is foreign branch income within the meaning of § 1.250(b)–1(c)(11). Accordingly, none of PRS's gain on the sale of property is included in DC's gross DEI or gross FDDEI under § 1.250(b)–1(e)(1).

(ii) *Example 2: Domestic partner sale to domestic partnership without a foreign branch*—(A) *Facts.* The facts are the same as in paragraph (e)(2)(i)(A) of this section (the facts in *Example 1*), except PRS is a domestic partnership that does not have a foreign branch within the meaning of § 1.904–4(f)(3)(iii).

(B) *Analysis.* DC's sale of property to PRS, a domestic partnership, is not a FDDEI sale because the sale is to a United States person. Therefore, the gross income from DC's sale to PRS is included in DC's gross DEI but is not included in its gross FDDEI. However, PRS's sale of other general property is a FDDEI sale, and therefore the gain of $20x is included in the gross DEI and gross FDDEI of PRS. Accordingly, DC includes its distributive share of PRS's gain from the sale in determining DC's gross DEI and gross FDDEI for the taxable year under § 1.250(b)–1(e)(1).

(f) *Substantiation for certain FDDEI transactions*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, for purposes of § 1.250(b)–4(d)(1)(ii)(C) (foreign use for sale of general property for resale), § 1.250(b)–4(d)(1)(iii) (foreign use for sale of general property subject to manufacturing, assembly, or processing outside the United States), § 1.250(b)–4(d)(2) (foreign use for sale of intangible property), and § 1.250(b)–5(e) (general services provided to business recipients located outside the United States), a transaction is a FDDEI transaction only if the taxpayer substantiates its determination of foreign use (in the case of sales of property) or location outside the United States (in the case of general services provided to a business recipient) as described in the applicable paragraph of § 1.250(b)–4(d)(3) or § 1.250(b)–5(e)(4). The substantiating documents must be in existence as of the FDII filing date with respect to the FDDEI transaction, and a taxpayer must provide the required substantiating documents within 30 days of a request by the Commissioner or another period as agreed between the Commissioner and the taxpayer.

(2) *Exception for small businesses.* Paragraph (f)(1) of this section, and the specific substantiation requirements described in the applicable paragraph of § 1.250(b)–4(d)(3) or § 1.250(b)–5(e)(4), do not apply to a taxpayer if the taxpayer and all related parties of the taxpayer, in the aggregate, receive less than $25,000,000 in gross receipts during the taxable year prior to the FDDEI transaction. If the taxpayer's prior taxable year was less than 12 months (a short period), gross receipts are annualized by multiplying the gross receipts for the short period by 365 and dividing the result by the number of days in the short period.

(3) *Treatment of certain loss transactions*—(i) *In general.* If a domestic corporation fails to satisfy the substantiation requirements described in the applicable paragraph of § 1.250(b)–4(d)(3) or § 1.250(b)–5(e)(4) with respect to a transaction (including in connection with a related party transaction described in § 1.250(b)–6), the gross income from the transaction will be treated as gross FDDEI if—

(A) In the case of a sale of property, the seller knows or has reason to know that property is sold to a foreign person for a foreign use (within the meaning of § 1.250(b)–4(d)(1) or (2));

(B) In the case of the provision of a general service to a business recipient, the renderer knows or has reason to know that a service is provided to a business recipient located outside the United States; and

(C) Not treating the transaction as a FDDEI transaction would increase the amount of the corporation's FDDEI for the taxable year relative to its FDDEI that would be determined if the transaction were treated as a FDDEI transaction.

(ii) *Reason to know*—(A) *Sales to a foreign person for a foreign use.* For purposes of paragraph (f)(3)(i)(A) of this section, a seller has reason to know that a sale is to a foreign person for a foreign use if the information received as part of the sales process contains information that indicates that the recipient is a foreign person or that the sale is for a foreign use, and the seller fails to obtain evidence establishing that the recipient is not in fact a foreign person or that the sale is not in fact for a foreign use. Information that indicates that a recipient is a foreign person or that the sale is for a foreign use includes, but is not limited to, a foreign phone number, billing address, shipping address, or place of residence; and, with respect to an entity, evidence that the entity is incorporated, formed, or managed outside the United States.

(B) *General services provided to a business recipient located outside the United States.* For purposes of paragraph (f)(3)(i)(B) of this section, a renderer has reason to know that the provision of a general service is to a business recipient located outside the United States if the information received as part of the sales process contains information that indicates that the recipient is a business recipient located outside the United States and the seller fails to obtain evidence establishing that the recipient is not in fact a business recipient located outside the United States. Information that indicates that a recipient is a business recipient includes, but is not limited to, indicia of a business status (such as ''LLC'' or ''Company,'' or similar indicia under applicable domestic or foreign law, in the name) or statements by the recipient indicating that it is a business. Information that indicates that a business recipient is located outside the United States includes, but is not limited to, a foreign phone number, billing address, and evidence that the entity or business is incorporated, formed, or managed outside the United States.

(iii) *Multiple transactions.* If a seller or renderer engages in more than one transaction described in paragraph (f)(3)(i) of this section in a taxable year, paragraph (f)(3)(i) of this section applies by comparing the corporation's FDDEI if each such transaction were not treated as a FDDEI transaction to its FDDEI if each such transaction were treated as a FDDEI transaction.

(iv) *Example.* The following example illustrates the application of this paragraph (f)(3).

(A) *Facts.* During a taxable year, DC, a domestic corporation, manufactures products A and B in the United States. DC sells product A and product B to Y, a foreign person that is a distributor, for $200x and $800x, respectively. DC knows or has reason to know that all of its sales of product A and product B will ultimately be sold to end users located outside the United States. Y provides DC with a statement that satisfies the substantiation requirement of paragraph (f)(1) of this section and § 1.250(b)–4(d)(3)(ii) that establishes that its sales of product B are for a foreign use but does not obtain substantiation establishing that any sales of product A are for a foreign use. DC's cost of goods sold is $450x. For purposes of determining gross FDDEI, under § 1.250(b)–1(d)(1) DC attributes $250x of cost of goods sold to product A and $200x of cost of goods sold to product B, and then attributes the cost of goods sold for each product ratably between the gross receipts of such product sold to foreign persons and the gross receipts of such product not sold to foreign persons. The manner in which DC attributes the cost of goods sold is a reasonable method. DC has no other items of income, loss, or deduction.

TABLE 1 TO PARAGRAPH (F)(3)(IV)(A)

	Product A	Product B	Total
Gross receipts	$200x	$800x	$1,000x
Cost of Goods Sold	250x	200x	450x
Gross Income (Loss)	(50x)	600x	550x

(B) *Analysis.* By not treating the sales of product A as FDDEI sales, the amount of DC's FDDEI would increase by $50x relative to its FDDEI if the sales of product A were treated as FDDEI sales. Accordingly, because DC knows or has reason to know that its sales of product A are to foreign persons for a foreign use, the sales of product A constitute FDDEI sales under paragraph (f)(3) of this section, and thus the $50x loss from the sale of product A is included in DC's gross FDDEI.

§ 1.250(b)–4 Foreign-derived deduction eligible income (FDDEI) sales.

(a) *Scope.* This section provides rules for determining whether a sale of property is a FDDEI sale. Paragraph (b) of this section defines a FDDEI sale. Paragraph (c) of this section provides rules for determining whether a recipient is a foreign person. Paragraph (d) of this section provides rules for determining whether property is sold for a foreign use. Paragraph (e) of this section provides a special rule for the sale of interests in a disregarded entity. Paragraph (f) of this section provides a rule regarding certain hedging transactions with respect to FDDEI sales.

(b) *Definition of FDDEI sale.* Except as provided in § 1.250(b)–6(c), the term *FDDEI sale* means a sale of general property or intangible property to a recipient that is a foreign person (see paragraph (c) of this section for presumption rules relating to determining foreign person status) and that is for a foreign use (as determined under paragraph (d) of this section). A sale of any property other than general property or intangible property is not a FDDEI sale.

(c) *Presumption of foreign person status*—(1) *In general.* The sale of property is presumed to be to a recipient that is a foreign person for purposes of paragraph (b) of this section if the sale is described in paragraph (c)(2) of this section. However, this presumption does not apply if the seller knows or has reason to know that the sale is not to a foreign person. A seller has reason to know that a sale is not to a foreign person if the information received as part of the sales process contains information that indicates that the recipient is not a foreign person and the seller fails to obtain evidence establishing that the recipient is in fact a foreign person. Information that indicates that a recipient is not a foreign person include, but are not limited to, a United States phone number, billing address, shipping address, or place of residence; and, with respect to an entity, evidence that the entity is incorporated, formed, or managed in the United States.

(2) *Sales of property.* A sale of a property is described in this paragraph (c)(2) if:

(i) The sale is a foreign retail sale;

(ii) In the case of a sale of general property that is not a foreign retail sale and the general property is delivered (such as through a commercial carrier) to the recipient or an end user, the shipping address of the recipient or end user is outside the United States;

(iii) In the case of a sale of general property that is not described in either paragraph (c)(2)(i) or (ii) of this section, the billing address of the recipient is outside the United States; or

(iv) In the case of a sale of intangible property, the billing address of the recipient is outside the United States.

(d) *Foreign use*—(1) *Foreign use for general property*—(i) *In general.* The sale of general property is for a foreign use for purposes of paragraph (b) of this section if the seller determines that the sale is for a foreign use under the rules of paragraph (d)(1)(ii) or (iii) of this section and the exception in paragraph (d)(1)(iv) of this section does not apply.

(ii) *Rules for determining foreign use*—(A) *Sales that are delivered to an end user by a carrier or freight forwarder.* Except as otherwise provided in this paragraph (d)(1)(ii)(A), a sale of general property (other than a sale of general property described in paragraphs (d)(1)(ii)(D) through (F) of this section) that is delivered through a carrier or freight forwarder to a recipient that is an end user is for a foreign use if the end user receives delivery of the general property outside the United States. However, a sale described in the preceding sentence is not treated as a sale to an end user for a foreign use if the sale is made with a principal purpose of having the property transported from its location outside the United States to a location within the United States for ultimate use or consumption.

(B) *Sales to an end user without the use of a carrier or freight forwarder.* With respect to sales that are not delivered through the use of a carrier or freight forwarder, a sale of general property (other than a sale of general property described in paragraphs (d)(1)(ii)(D) through (F) of this section) to a recipient that is an end user is for a foreign use if the property is located outside the United States at the time of the sale (including as part of foreign retail sales).

(C) *Sales for resale.* A sale of general property (other than a sale of general property described in paragraphs (d)(1)(ii)(D) through (F) of this section) to a recipient (such as a distributor or retailer) that will resell the general property is for a foreign use if the

general property will ultimately be sold to end users outside the United States (including in foreign retail sales) and such sales to end users outside the United States are substantiated under paragraph (d)(3)(ii) of this section. In the case of sales of a fungible mass of general property, the taxpayer may presume that the proportion of its sales that are ultimately sold to end users outside the United States is the same as the proportion of the recipient's resales of that fungible mass to end users outside the United States.

(D) *Sales of digital content.* A sale of general property that primarily contains digital content that is transferred electronically rather than in a physical medium is for a foreign use if the end user downloads, installs, receives, or accesses the purchased digital content on the end user's device outside the United States (see § 1.250(b)–5(d)(2) and (e)(2)(iii) for rules that apply in the case of digital content that is not purchased in a sale but is electronically supplied as a service). If information about where the digital content is downloaded, installed, received, or accessed (such as the device's IP address) is unavailable, and the gross receipts from all sales with respect to the end user (which may be a business) are in the aggregate less than $50,000, a sale of general property described in the preceding sentence is for a foreign use if it is to an end user that has a billing address located outside the United States.

(E) *Sales of international transportation property used for compensation or hire.* A sale of international transportation property used for compensation or hire is for a foreign use if the end user registers the property with a foreign jurisdiction.

(F) *Sales of international transportation property not used for compensation or hire.* A sale of international transportation property not used for compensation or hire is for a foreign use if the end user registers the property in a foreign jurisdiction and hangars or stores the property primarily outside the United States.

(iii) *Sales for manufacturing, assembly, or other processing*—(A) *In general.* A sale of general property is for a foreign use if the sale is to a foreign unrelated party that subjects the property to manufacture, assembly, or other processing outside the United States and such manufacturing, assembly, or other processing outside the United States is substantiated under paragraph (d)(3)(iii) of this section. Property is subject to manufacture, assembly, or other processing only if the property is physically and materially changed (as described in paragraph (d)(1)(iii)(B) of this section) or the property is incorporated as a component into another product (as described in paragraph (d)(1)(iii)(C) of this section).

(B) *Property subject to a physical and material change.* The determination of whether general property is subject to a physical and material change is made based on all the relevant facts and circumstances. General property is subject to a physical and material change if it is substantially transformed and is distinguishable from and cannot be readily returned to its original state.

(C) *Property incorporated into a product as a component.* General property is a component incorporated into another product if the incorporation of the general property into another product involves activities that are substantial in nature and generally considered to constitute the manufacture, assembly, or processing of property based on all the relevant facts and circumstances. However, general property is not considered a component incorporated into another product if it is subject only to packaging, repackaging, labeling, or minor assembly operations. In addition, general property is treated as a component if the seller expects, using reliable estimates, that the fair market value of the property when it is delivered to the recipient will constitute no more than 20 percent of the fair market value of the finished good into which the general property is directly or indirectly incorporated when the finished good is sold to end users (the ''20-percent rule''). If the property could be incorporated into a number of different finished goods, a reliable estimate of the fair market value of the finished good may include the average fair market value of a representative range of such goods. For purposes of the 20-percent rule, all general property that is sold by the seller and incorporated into the finished good is treated as a single item of property if the seller sells the property to the recipient and the seller knows or has reason to know that the components will be incorporated into a single item of property (for example, where multiple components are sold as a kit). A seller knows or has reason to know that the components will be incorporated into a single item of property if the information received as part of the sales process indicates that the components will be included in the same second product or the nature of the components compels inclusion into the second product and the seller fails to obtain evidence to the contrary.

(iv) *Sales of property subject to manufacturing, assembly, or other processing in the United States.* If the seller sells general property to a recipient (other than a related party) for manufacturing, assembly, or other processing within the United States, such property is not sold for a foreign use even if the requirements of paragraph (d)(1)(ii) or (iii) of this section are subsequently satisfied. See § 1.250(b)–6(c) for rules governing sales of general property to a foreign person that is a related party. Property is subject to manufacture, assembly, or other processing only if the property is physically and materially changed (as described in paragraph (d)(1)(iii)(B) of this section) or the property is incorporated as a component into another product (as described in paragraph (d)(1)(iii)(C) of this section).

(v) *Examples.* The following examples illustrate the application of this paragraph (d)(1).

(A) *Assumed facts.* The following facts are assumed for purposes of the examples—

(*1*) DC is a domestic corporation.

(*2*) FP is a foreign person that is a foreign unrelated party with respect to DC.

(*3*) To the extent a sale is for a foreign use, any applicable substantiation requirements described in paragraph (d)(3)(ii) or (iii) of this section are satisfied.

(B) *Examples*—

(*1*) *Example 1: Manufacturing outside the United States*—(*i*) *Facts.* DC sells batteries for $18x to FP. DC expects that FP will insert the batteries into tablets as part of the process of assembling tablets outside the United States. While the tablets are manufactured in a way that end users would not easily be able to remove the batteries, the batteries could be removed from the tablets and would resemble their original state following the removal. The finished tablets will be sold to end users within and outside the United States. DC's batteries are used in two types of tablets, Tablet A and Tablet B. Based on an economic analysis, DC determines that the fair market value of Tablet A is $90x and the fair market value of Tablet B is $110x. FP informs DC that the number of sales of Tablet A is approximately equal to the number of sales of Tablet B.

(*ii*) *Analysis.* Because the batteries could be removed from the tablets and be returned to their original state, the insertion of the batteries into the tablets does not constitute a physical and material change described in paragraph (d)(1)(iii)(B) of this section. However, the average fair market value of a representative range of tablets that incorporate the batteries is $100x (the average of $90x for Tablet A and $110x for Tablet B because their sales are approximately equal), and $18x is less than 20 percent of $100x. Therefore, the batteries are considered components of the tablets and treated as subject to manufacture, assembly, or other processing outside the United States. See paragraphs (d)(1)(iii)(A) and (C) of this section. As a result, notwithstanding that

some tablets incorporating the batteries may be sold to an end user in the United States, DC's sale of batteries is considered for a foreign use. Accordingly, DC's sale of batteries to FP is for a foreign use under paragraph (d)(1)(iii)(A) and (C) of this section, and the sale is a FDDEI sale.

(*2*) *Example 2: Manufacturing outside the United States*—(*i*) *Facts.* The facts are the same as in paragraph (d)(1)(v)(B)(*1*) of this section (the facts in *Example 1*), except FP purchases the batteries from DC for $25x. In addition, FP purchased other components of tablets from other parties. FP has a substantial investment in machinery and tools that are used to assemble tablets.

(*ii*) *Analysis.* Even though the fair market value of the batteries that FP purchases from DC and incorporates into the tablets exceeds 20 percent of the fair market value of the tablets, because the batteries are used by FP in activities that are substantial in nature and generally considered to constitute the manufacture, assembly or other processing of property, the batteries are components of the tablets. As a result, DC's sale of property to FP is still for a foreign use under paragraph (d)(1)(iii)(A) and (C) of this section, and the sale is a FDDEI sale.

(*3*) *Example 3: Sale of products to distributor outside the United States*—(*i*) *Facts.* DC sells smartphones to FP, a distributor of electronics located within Country A. The sales contract between DC and FP provides that FP may sell the smartphones it purchases from DC only to specified retailers located within Country A. The specified retailers only sell electronics, including smartphones, in foreign retail sales.

(*ii*) *Analysis.* Although FP does not sell the smartphones it purchases from DC to end users, FP sells to retailers that sell the smartphones in foreign retail sales. All of the sales of smartphones from DC to FP are sales of general property for a foreign use under paragraph (d)(1)(ii)(C) of this section because FP is only allowed to sell the smartphones to retailers who sell such property in foreign retail sales. As a result, DC's sales of smartphones to FP are FDDEI sales.

(*4*) *Example 4: Sale of a fungible mass of products*—(*i*) *Facts.* DC and persons other than DC sell multiple units of printer paper that is considered fungible general property to FP during the taxable year. FP is a distributor that sells paper to retail stores within and outside the United States. FP informs DC that approximately 25 percent of FP's sales of the paper are to retail stores located outside of the United States for foreign retail sales.

(*ii*) *Analysis.* The sale of paper to FP is for a foreign use to the extent that the paper will be sold to end users located outside the United States under paragraph (d)(1)(ii)(C) of this section. Because a portion of DC's sales to FP are not for a foreign use, DC must determine the amount of paper that is sold for a foreign use. Based on the information provided by FP about its own sales, DC determines under paragraph (d)(1)(ii)(C) of this section that 25 percent of the total units of paper that is fungible general property that FP purchased from all persons in the taxable year will ultimately be sold to end users located outside the United States. Accordingly, DC satisfies the test for a foreign use under paragraph (d)(1)(ii)(C) of this section with respect to 25 percent of its sales of the paper to FP.

(*5*) *Example 5: Limited use license of copyrighted computer software*—(*i*) *Facts.* DC provides FP with a limited use license to copyrighted computer software in exchange for an annual fee of $100x. The limited use license restricts FP's use of the computer software to 100 of FP's employees, who download the software onto their computers. The limited use license prohibits FP from using the computer software in any way other than as an end user, which includes prohibiting sublicensing, selling, reverse engineering, or modifying the computer software. All of FP's employees download the software onto computers that are physically located outside the United States.

(*ii*) *Analysis.* The software licensed to FP is digital content as defined in § 1.250(b)–3(b)(1), and is downloaded by an end user as defined in § 1.250(b)–3(b)(2). Accordingly, because the software is downloaded solely onto computers outside the United States, DC's license to FP is for a foreign use and therefore a FDDEI sale under paragraph (d)(1)(ii)(D) of this section. The entire $100x of the license fee is included in DC's gross FDDEI for the taxable year.

(*6*) *Example 6: Limited use license of copyrighted computer software used within and outside the United States*—(*i*) *Facts.* The facts are the same as in paragraph (d)(1)(v)(B)(*5*) of this section (the facts in *Example 5*), except that FP has offices both within and outside the United States, and DC's internal records indicates that 50 percent of the downloads of the software are onto computers located outside the United States.

(*ii*) *Analysis.* Because 50 percent of the downloads of the software are onto computers located outside the United States, a portion of DC's license to FP is for a foreign use and therefore such portion is a FDDEI sale. The $50x of license fee derived with respect to such portion is included in DC's gross FDDEI for the taxable year.

(*7*) *Example 7: Sale of a copyrighted article*—(*i*) *Facts.* DC sells copyrighted music available for download on its website. Once downloaded, the recipient listens to the music on electronic devices that do not need to be connected to the internet. DC has data that an individual accesses the website to purchase a song for download on a device located outside the United States. The terms of the sale permit the recipient to use the song for personal use, but convey no other rights to the copyrighted music to the recipient.

(*ii*) *Analysis.* The music acquired through download is digital content as defined in § 1.250(b)–3(b)(1). Because the recipient acquires no ownership in copyright rights to the music, the sale is considered a sale of a copyrighted article, and thus is a sale of general property. See § 1.250(b)–3(b)(10) and (11). As a result, the sale is considered for a foreign use under paragraph (d)(1)(ii)(D) of this section because the digital content was installed, received, or accessed on the end user's device outside the United States. The income derived with respect to the sale of the music is included in DC's gross FDDEI for the taxable year. See § 1.250(b)–5(d)(3) for an example of digital content provided to consumers as a service rather than as a sale.

(2) *Foreign use for intangible property*—(i) *In general.* A sale of rights to exploit intangible property solely outside the United States is for a foreign use. A sale of rights to exploit intangible property solely within the United States is not for a foreign use. A sale of rights to exploit intangible property worldwide is partially for a foreign use and partially not for a foreign use. Whether intangible property is exploited within versus outside the United States is determined based on revenue earned from end users located within versus outside the United States. Therefore, a sale of rights to exploit intangible property both within and outside the United States is for a foreign use in proportion to the revenue earned from end users located outside the United States over the total revenue earned from the exploitation of the intangible property. A sale of intangible property will be treated as a FDDEI sale only if the substantiation requirements of paragraph (d)(3)(iv) of this section are satisfied. For rules specific to determining end users and revenue earned from end users for intangible property used in sales of general property, provision of services, research and development, or consisting of a manufacturing method or process, see paragraph (d)(2)(ii) of this section.

(ii) *Determination of end users and revenue earned from end users*—(A) *Intangible property embedded in general property or used in connection with the sale of general property.* If intangible property is embedded in general property that is sold, or used in connection with a sale of general property, then the end user of the intangible property is the end user of the general property. Revenue is earned from the end user of the general property outside the United States to the extent the sale of the general property is for a foreign use under paragraph (d)(1)(ii) of this section.

(B) *Intangible property used in providing a service.* If intangible property is used to provide a service, then the end user of that intangible property is the recipient, consumer, or business recipient of the service or, in the case of a property service or a transportation service that involves the transportation of property, the end user is the owner of the property on which such service is being performed. Such end users are treated as located outside the United States only to the extent the service qualifies as a FDDEI service

under § 1.250(b)–5. Therefore, in the case of a recipient of a sale of intangible property that uses such intangible property to provide a property service that qualifies as a FDDEI service to another person, that person is the end user and is treated as located outside the United States.

(C) *Intangible property consisting of a manufacturing method or process*—(*1*) *In general.* Except as provided in paragraph (d)(2)(ii)(C)(*2*) of this section, if intangible property consists of a manufacturing method or process (as defined in paragraph (d)(2)(ii)(C)(*3*) of this section) and is sold to a foreign unrelated party (including in a sale by a foreign related party), then the foreign unrelated party is treated as an end user located outside the United States, unless the seller knows or has reason to know that the manufacturing method or process will be used in the United States, in which case the foreign unrelated party is treated as an end user located within the United States. A seller has reason to know that the manufacturing method or process will be used in the United States if the information received from the recipient as part of the sales process contains information that indicates that the recipient intends to use the manufacturing method or process in the United States and the seller fails to obtain evidence establishing that the recipient does not intend to use the manufacturing method or process in the United States.

(*2*) *Exception for certain manufacturing arrangements.* A sale of intangible property consisting of a manufacturing method or process (including a sale by a foreign related party) to a foreign unrelated party for use in manufacturing products for or on behalf of the seller or any person related to the seller does not qualify as a sale to a foreign unrelated party for purposes of determining the end user under paragraph (d)(2)(ii)(C)(*1*) of this section.

(*3*) *Manufacturing method or process.* For purposes of this section, a manufacturing method or process consists of a sequence of actions or steps that comprise an overall method or process that is used to manufacture a product or produce a particular manufacturing result, which may be in the form of a patent or know-how. Intangible property consisting of the right to make and sell an item of property is not a manufacturing method or process, whereas intangible property consisting of the right to apply a series of actions or steps to be performed to achieve a particular manufacturing result is a manufacturing method or process. For example, a utility or design patent on an article of manufacture, machine, composition of matter, design, or providing the right to sell equipment to perform a process is not a manufacturing method or process, whereas a utility patent covering a method or process of manufacturing is a manufacturing method or process for purposes of this section.

(D) *Intangible property used in research and development.* If intangible property (primary IP) is used to develop new or modify other intangible property (secondary IP), then the end user of the primary IP is the end user (applying paragraph (d)(2)(ii)(A), (B), or (C) of this section) of the secondary IP.

(iii) *Determination of revenue for periodic payments versus lump sums*—(A) *Sales in exchange for periodic payments.* In the case of a sale of intangible property, other than intangible property consisting of a manufacturing method or process that is sold to a foreign unrelated party, to a recipient in exchange for periodic payments, the extent to which the sale is for a foreign use is determined annually based on the actual revenue earned by the recipient from any use of the intangible property for the taxable year in which a periodic payment is received. If actual revenue earned by the recipient cannot be obtained after reasonable efforts, then estimated revenue earned by a recipient that is not a related party of the seller from the use of the intangible property may be used based on the principles of paragraph (d)(2)(iii)(B) of this section.

(B) *Sales in exchange for a lump sum.* In the case of a sale of intangible property, other than intangible property consisting of a manufacturing method or process that is sold to a foreign unrelated party, for a lump sum, the extent to which the sale is for a foreign use is determined based on the ratio of the total net present value of revenue the seller would have expected to earn from the exploitation of the intangible property outside the United States to the total net present value of revenue the seller would have expected to earn from the exploitation of the intangible property. In the case of a recipient that is a foreign unrelated party, net present values of revenue that the recipient expected to earn from the exploitation of the intangible property within and outside the United States may also be used if the seller obtained such revenue data from the recipient near the time of the sale and such revenue data was used to negotiate the lump sum price paid for the intangible property. Net present values must be determined using reliable inputs including, but not limited to, reliable revenue, expenses, and discount rates. The extent to which the inputs are used by the parties to determine the sales price agreed to between the seller and a foreign unrelated party purchasing the intangible property will be a factor in determining whether such inputs are reliable. If the intangible property is sold to a foreign related party, the reliability of the inputs used to determine net present values and the net present values are determined under section 482.

(C) *Sales to a foreign unrelated party of intangible property consisting of a manufacturing method or process.* In the case of a sale to an unrelated foreign party of intangible property consisting of a manufacturing method or process, the revenue earned from the end user is equal to the amount received from the recipient in exchange for the manufacturing method or process. In the case of a bundled sale of intangible property consisting of a manufacturing method or process and intangible property not consisting of a manufacturing method or process, the revenue earned from the intangible property consisting of the manufacturing method or process equals the total amount paid for the bundled sale multiplied by the proportion that the value of the manufacturing method or process bears to the total value of the intangible property. The value of the manufacturing method or process to the total value of the intangible property must be determined using the principles of section 482.

(iv) *Examples.* The following examples illustrate the application of this paragraph (d)(2).

(A) *Assumed facts.* The following facts are assumed for purposes of the examples—

(*1*) DC is a domestic corporation.

(*2*) Except as otherwise provided, FP and FP2 are foreign persons that are foreign unrelated parties with respect to DC.

(*3*) All of DC's income is DEI.

(*4*) Except as otherwise provided, the substantiation requirements described in paragraph (d)(3)(iv) of this section are satisfied.

(*5*) Except as otherwise provided, inputs used to determine the net present values of the revenue are reliable.

(B) *Examples*—

(*1*) *Example 1: License of worldwide rights with actual revenue data from recipient*—(*i*) *Facts.* DC licenses to FP worldwide rights to the copyright to composition A in exchange for annual royalties of 60 percent of revenue from FP's sales of composition A. FP sells composition A to customers through digital downloads from servers. In the taxable year, FP earns $100x in revenue from sales of

copies of composition A to customers, of which $60x is from customers located in the United States and the remaining $40x is from customers located outside the United States. FP provides DC with reliable records showing the amount of revenue earned in the taxable year from sales of composition A to establish the royalties owed to DC. These records also provide DC with the amount of revenue earned from sales of composition A to customers located within the United States.

(*ii*) *Analysis.* FP is not the end user of the copyright to composition A under paragraph (d)(2)(ii)(A) of this section because the copyright is used in the sale of general property (the sale of copyrighted articles to customers). The customers that purchase a copy of composition A from FP are the end users (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(A) of this section) because those customers are the recipients of composition A when sold as general property. Based on the actual revenue earned by FP from sales of composition A, 40 percent ($40x/$100x) of the revenue generated by the copyright during the taxable year is earned outside the United States. Accordingly, a portion of DC's license to FP is for a foreign use under paragraph (d)(2) of this section and therefore such portion is a FDDEI sale. The $24x of royalty (0.40 x $60x of total royalties owed to DC during the taxable year) derived with respect to such portion is included in DC's gross FDDEI for the taxable year.

(*2*) *Example 2: Fixed annual payments for worldwide rights without actual revenue data from recipient*—(*i*) *Facts.* The facts are the same as in paragraph (d)(2)(iv)(B)(*1*)(*i*) of this section (the facts in *Example 1*), except FP pays DC a fixed annual payment of $60x each year for the worldwide rights to the copyright to composition A and does not provide DC with data showing how much revenue FP earned from sales of composition A, even after DC requests that FP provide it with such information. DC also is unable to determine how much revenue FP earned from sales of composition A to customers within the United States from the data it has with respect to FP and publicly available data with respect to FP. However, DC's economic analysis of the revenue DC expected it could earn annually from use of composition A as part of determining the annual payments DC would receive from FP from the license of composition A supports a determination that 40 percent of sales of composition A during the tax year would be to customers located outside the United States. During an examination of DC's return for the taxable year, DC provides the IRS with data explaining the economic analysis, inputs, and results from its valuation of composition A used in determining the amount of annual payments agreed to by DC and FP.

(*ii*) *Analysis.* For the same reasons provided in paragraph (d)(2)(iv)(B)(*1*)(*ii*) of this section (the analysis in *Example 1*), the customers that purchase copies of composition A from FP are the end users. DC is allowed to use reliable economic analysis to estimate revenue earned by FP from the use of the copyright to composition A under paragraph (d)(2)(iii)(A) of this section because DC was unable to obtain actual revenue earned by FP from use of the copyright to composition A during the taxable year after reasonable efforts to obtain the actual revenue data. Based on DC's economic analysis, a portion of DC's license to FP is for a foreign use under paragraph (d)(2) of this section and therefore such portion is a FDDEI sale. $24x of the $60x fixed payment to DC (0.40 x $60x) is included in DC's gross FDDEI for the taxable year.

(*3*) *Example 3: Sale of patent rights protected in the United States and other countries; use of financial projections in sale to foreign unrelated party*—(*i*) *Facts.* DC owns a patent for an active pharmaceutical ingredient (''API'') approved for treatment of disease A (''indication A'') in the United States and in Countries A, B, and C. The patent is registered in the United States and in Countries A, B, and C. DC sells to FP all of its patent rights to the API for indication A for a lump sum payment of $1,000x. DC has no basis in the patent rights. To determine the sales price for the patent rights, DC projected that the net present value of the revenue it would earn from selling a pharmaceutical product incorporating the API for indication A was $5,000x, with 15 percent of the net present value of revenue earned from sales within the United States and 85 percent of the net present value of revenue earned from sales outside the United States. DC did not obtain revenue projections from the recipient.

(*ii*) *Analysis.* FP is not the end user of the patent under paragraph (d)(2)(ii)(A) of this section because the patent is used in the sale of general property (the sale of pharmaceutical products to customers) and FP is not the recipient of that general property. The unrelated party customers that purchase the finished pharmaceutical product from FP are the end users (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(A) of this section) because those customers are the unrelated party recipients of the pharmaceutical product when sold as general property. Based on the financial projections DC used to determine the sales price of the patent that FP purchased, a portion of DC's sale to FP is for a foreign use under paragraph (d)(2) of this section and such portion is a FDDEI sale. The $850x (85 percent × $1,000x) of gain derived with respect to such portion is included in DC's gross FDDEI for the taxable year.

(*4*) *Example 4: Sale of patent rights protected in the United States and other countries; use of financial projections in sale to foreign related party*—(*i*) *Facts.* The facts are the same as in paragraph (d)(2)(iv)(B)(*3*)(*i*) of this section (the facts in *Example 3*), except that FP is a foreign related party with respect to DC, and DC projected that the net present value of the revenue it would earn from selling a pharmaceutical product incorporating the API for indication A would result in 1 percent of the revenue earned from sales within the United States and 99 percent of the revenue earned from sales outside the United States. During the examination of DC's return for the taxable year, the IRS determines that DC's substantiation allocating the projected revenue from sales within the United States and outside the United States does not reflect reliable inputs to determine the net present values of revenues under section 482, but determines that the total lump sum price FP paid for DC's patent rights is an arm's length price. The IRS determines that the most reliable net present values of revenue DC would have earned from sales within the United States and outside the United States is $750x and $4250x, respectively.

(*ii*) *Analysis.* For the same reasons provided in paragraph (d)(2)(iv)(B)(*3*)(*ii*) of this section (the analysis in *Example 3*), the customers that purchase the finished pharmaceutical product from FP are the end users. Under paragraph (d)(2)(iii)(B) of this section, the reliability of the inputs DC used to determine the net present values and the net present values are determined under section 482. Based on the sales price of the patent that FP purchased and the IRS-determined net present values of revenue DC would have earned from sales within the United States and outside the United States, a portion of DC's sale to FP is for a foreign use under paragraph (d)(2) of this section and such portion is a FDDEI sale. DC is allowed to include $850x (($4250x divided by $5000x) × $1,000x) of gain in DC's gross FDDEI for the taxable year.

(*5*) *Example 5: Sale of patent of manufacturing method or process protected in the United States and other countries; foreign unrelated party*—(*i*) *Facts.* DC owns the worldwide rights to a patent covering a process for refining crude oil. DC sells to FP the right to DC's patented process for refining crude oil for a lump sum payment of $100x. DC has no basis in the patent rights. DC does not know or have reason to know that FP will use the patented process to refine crude oil within the United States or will sell or license the rights to the patent to a person to refine crude oil within the United States.

(*ii*) *Analysis.* DC's patent covering a process for refining crude oil is a manufacturing method or process as defined in paragraph (d)(2)(ii)(C)(*3*) of this section. Under paragraph (d)(2)(ii)(C)(*1*) of this section, FP is treated as the end user of the patent, and is treated as located outside the United States because FP is a foreign unrelated party and DC does not know or have reason to know that the patented process will be used in the United States. As a result, all of the sale to FP is for a foreign use under paragraph (d)(2) of this section and therefore is a FDDEI sale. The entire $100x lump sum payment is included in DC's gross FDDEI for the taxable year.

(*6*) *Example 6: License of intangible property that includes a patented manufacturing method or process protected in the United States and other countries; foreign unrelated party*—(*i*) *Facts.* DC owns worldwide rights to patents, know-how, and a trademark and tradename for product Z. The patents consist of: a patent covering the right to make, use, and sell product Z (article of manufacture), a patent covering the rights to make, use, and sell a composition of substances used in certain components of product Z (composition of matter), and a patent covering the right to use a manufacturing process consisting of a series

of manufacturing steps to manufacture product Z (manufacturing method or process as defined in paragraph (d)(2)(ii)(C)(*3*) of this section) and to sell the product Z that FP manufactures using the manufacturing method or process. The know-how consists entirely of manufacturing know-how used to implement the manufacturing steps that comprise the manufacturing method or process. DC licenses the worldwide rights to the patents, know-how, and the trademark and tradename for product Z to FP in exchange for annual royalties of 60 percent of revenue from sales of product Z. FP manufactures product Z in country X and sells product Z to DC2, a domestic corporation and unrelated party to DC and FP, for resale to customers located within the United States. FP also sells product Z to FP2, a foreign unrelated party with respect to DC and FP, for resale to customers located outside the United States. During the taxable year, FP sells to DC2 $140x of product Z. Also, during the taxable year, FP sells to FP2 $60x of product Z. DC determines under the principles of section 482 that the licensed know-how and the patented manufacturing method or process comprise 10 percent of the arm's length price of the intangible property DC licenses to FP.

(*ii*) *Analysis*—(A) *End users.* Under paragraph (d)(2)(ii)(C)(*1*) of this section, FP is treated as the end user of the patent covering the right to use the manufacturing process and the manufacturing know-how used to implement the manufacturing method or process, and is treated as located outside the United States because FP is a foreign unrelated party and DC does not know or have reason to know that the patented process and know-how will be used in the United States. DC2, FP, and FP2 are not the end users of the remaining intangible property under paragraph (d)(2)(ii)(A) of this section because that intangible property is used in the sale of general property (the sale of product Z) and DC2, FP, and FP2 are not the end users of that general property. The unrelated party customers that purchase product Z from DC2 and FP2 are the end users (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(A) of this section) because those customers are the unrelated party recipients of product Z.

(B) *Foreign use.* Under paragraph (d)(2)(ii)(A) of this section, revenue from royalties paid for the intangible property other than the manufacturing method or process is earned from end users outside the United States to the extent the sale of the general property is for a foreign use under paragraph (d)(1) of this section. FP2 is a reseller of product Z to end users outside the United States, so all sales of product Z to FP2 are for a foreign use under paragraph (d)(1)(ii)(C) of this section. Because DC has determined that 10 percent of the value of the intangible property consists of a manufacturing method or process (as defined in paragraph (d)(2)(ii)(C)(*3*) of this section) used to manufacture product Z, $12x of the $120x royalty FP pays to DC during the taxable year is for foreign use ($120x total royalty × 0.10) based on the location of FP's manufacturing utilizing the know-how or all of the sequence of actions that comprise the manufacturing method or process under paragraph (d)(2)(ii)(C)(*3*) of this section. Based on the sales of product Z within and outside the United States, $32.4x of the royalties FP pays DC for rights to the licensed intangible property during the taxable year (($60x of revenue from sales to FP2 for resale to customers located outside the United States divided by $200x total worldwide sales revenue FP receives from DC2 and FP2) × ($120x total royalties less $12 of those royalties attributable to the manufacturing method or process)) qualifies as income earned from the sale of intangible property for a foreign use under paragraph (d)(2) of this section and therefore such portion is a FDDEI sale. As a result, $44.40x of royalties ($12x + $32.40x) is included in DC's gross FDDEI for the taxable year.

(*7*) *Example 7: License of intangible property that includes a patented manufacturing method or process protected in the United States and other countries; foreign related party with third-party manufacturer*—(*i*) *Facts.* The facts are the same as in paragraph (d)(2)(iv)(B)(*6*)(*i*) of this section (the facts in *Example 6*), except that FP is a foreign related party with respect to DC and FP engages FP2, a foreign unrelated party, to manufacture product Z. FP sublicenses to FP2 the rights to the intangible property FP licenses from DC solely to manufacture product Z and sell product Z to FP. FP2 manufactures product Z in country Y and sells all of product Z it manufactures to FP. During the taxable year, FP sold $80x of product Z to DC2, which DC2 resold to customers located within the United States. Also, during the taxable year, FP sold $120x of product Z to customers located outside the United States.

(*ii*) *Analysis*—(A) *End users.* Under paragraph (d)(2)(ii)(C)(*1*) of this section, FP is not treated as the end user of the patent covering the right to use the manufacturing process and the manufacturing know-how used to implement the manufacturing method or process because FP is a foreign related party with respect to DC. Under paragraph (d)(2)(ii)(C)(*2*) of this section, FP2 is also not treated as the end user of the patent covering the right to use the manufacturing process and the manufacturing know-how used to implement the manufacturing method or process because FP2 is using that intangible property to manufacture product Z for FP. DC2 is also not treated as the end user of the patent covering the right to use the manufacturing process and the manufacturing know-how used to implement the manufacturing method or process because DC2 does not use the patent or know-how in manufacturing. DC2, FP, and FP2 are not the end users of the remaining intangible property under paragraph (d)(2)(ii)(A) of this section because that intangible property is used in the sale of general property (the sale of product Z) and DC2, FP, and FP2 are not the end users of that general property. The unrelated party customers that purchase the Product Z from DC2 and FP are the end users (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(A) of this section) of the intangible property because those customers are the persons that ultimately use or consume product Z.

(B) *Foreign use.* Based on the sales of product Z to customers located within and outside the United States, $72x of the royalties FP pays DC for rights to the licensed intangible property during the taxable year (($120x of revenue from sales to customers located outside the United States divided by $200x total worldwide sales revenue) × $120x total royalties) qualifies as income earned from the sale of intangible property for a foreign use under paragraph (d)(2) of this section and therefore such portion is a FDDEI sale. As a result, $72x of royalties is included in DC's gross FDDEI for the taxable year.

(*8*) *Example 8: Deemed sale in exchange for contingent payments under section 367(d)*—(*i*) *Facts.* DC owns 100 percent of the stock of FP, a foreign related party with respect to DC. FP manufactures and sells product A. For the taxable year, DC contributes to FP exclusive worldwide rights to patents, trademarks, know-how, customer lists, and goodwill and going concern value (collectively, intangible property) related to product A in an exchange described in section 351. DC is required to report an annual income inclusion on its Federal income tax return based on the productivity, use, or disposition of the contributed intangible property under section 367(d). DC includes a percentage of FP's revenue in its gross income under section 367(d) each year. In the current taxable year, FP earns $1,000x of revenue from sales of product A. Based on reliable sales records kept by FP for the taxable year, $300x of FP's revenue is earned from sales of product A to customers within the United States, and $700x of its revenue is earned from sales of product A to customers outside the United States.

(*ii*) *Analysis.* DC's deemed sale of the intangible property to FP in exchange for payments contingent upon the productivity, use, or disposition of the intangible property related to product A under section 367(d) is a sale for purposes of section 250 and this section. See § 1.250(b)–3(b)(16). Based on FP's sales records for the taxable year, 70 percent of DC's deemed sale to FP is for a foreign use, and 70 percent of DC's income inclusion under section 367(d) derived with respect to such portion is included in DC's gross FDDEI for the taxable year.

(*9*) *Example 9: License of intangible property followed by a sale of general property in which the intangible property is embedded; unrelated parties*—(*i*) *Facts.* DC owns the worldwide rights to a patent on a silicon chip used in computers, tablets, and smartphones. The patent does not qualify as a manufacturing method or process (as defined in paragraph (d)(2)(ii)(C)(*3*) of this section). DC licenses the worldwide rights to the patent to FP in exchange for annual royalties of 30 percent of revenue from sales of the silicon chips. During the taxable year, FP manufactures silicon chips protected by the patent and sells all of those chips to FP2 for $1,000x. FP2 also purchases similar silicon chips from other suppliers. FP2 uses the silicon chips in computers, tablets, smartphones, and motherboards that FP2 manufactures in country X and sells to its customers located within the United States and foreign countries. For purposes of this

example, FP2's manufacturing qualifies as subjecting the silicon chips to manufacture, assembly, or other processing outside the United States as provided in paragraph (d)(1)(iii) of this section.

(*ii*) *Analysis.* FP is not the end user or treated as an end user (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(A) of this section) because FP is not the unrelated party recipient of the general property in which the patent is embedded, and the patent does not qualify as a manufacturing method or process. Under paragraph (d)(2)(ii)(A) of this section, revenue from royalties paid for the patent is earned from end users outside the United States to the extent the sale of the general property is for a foreign use under paragraph (d)(1) of this section. Because FP2 is subjecting the silicon chips to manufacture, assembly, or other processing outside the United States, the revenue from royalties FP pays to DC qualifies for foreign use based on the location of FP2's manufacturing and qualifies as a FDDEI sale. As a result, the entire $300x of annual royalties paid by FP to DC during the taxable year is included in DC's gross FDDEI for the taxable year.

(*10*) *Example 10: License of intangible property followed by a sale of general property in which the intangible property is embedded; related parties*—(*i*) *Facts.* The facts are the same as in paragraph (d)(2)(iv)(B)(*9*)(*i*) of this section (the facts in *Example 9*), except that FP and FP2 are foreign related parties with respect to DC. FP2 sells and ships computers, tablets, and smartphones it manufactures with the silicon chips it purchases from FP to unrelated party wholesalers located within and outside the United States. The wholesalers within the United States only sell to retailers located within the United States and the wholesalers outside the United States only sell to retailers located outside the United States. The retailers within the United States only sell to customers located within the United States and the retailers located outside the United States only sell to customers located outside the United States. FP2 earns $15,000x of revenue from sales to unrelated party wholesalers located outside the United States and $10,000x of revenue from sales to unrelated party wholesalers located within the United States. FP2 also sells and ships motherboards with the silicon chips it purchases from FP to unrelated party manufacturers located outside the United States. FP2 does not sell motherboards with the silicon chips it purchases from FP to unrelated party manufacturers located within the United States. FP2 earns $5,000x of revenue from the sales of these motherboards to manufacturers located outside the United States. For purposes of this example, these manufacturers subject the motherboards to manufacture, assembly, or other processing outside the United States as provided in paragraph (d)(1)(iii) of this section.

(*ii*) *Analysis.* FP is not the end user or treated as an end user (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(A) of this section) of the intangible property because FP is not the end user of the general property in which the patent is embedded (the silicon chips). FP2 is also not the end user (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(A) of this section) of the intangible property because FP2 is not the end user of the silicon chips. Under paragraph (d)(2)(ii)(A) of this section, the customers of the retailers that purchase from the unrelated party wholesalers are the end users. Because the wholesalers located outside the United States only sell to retailers located outside the United States that sell to end users located outside the United States, the location of the wholesalers is a reliable basis for determining the location of the end users. Revenue from royalties paid for the patent is earned from end users outside the United States to the extent the sale of the general property is for a foreign use under paragraph (d)(1) of this section. A portion of the sales to the unrelated party wholesalers qualify as foreign use under paragraph (d)(1) of this section and the sales to the unrelated party manufacturers qualify as foreign use under paragraph (d)(1)(iii) of this section. Accordingly, revenue from royalties FP pays to DC is from a FDDEI sale to the extent of such sales to the unrelated party manufacturers and such potion of sales to unrelated party wholesalers that qualify for foreign use. As a result, $200x of annual royalties paid by FP to DC during the taxable year (((($15,000x of sales to wholesalers located outside the United States plus $5,000x of sales to manufacturers located outside the United States) divided by $30,000x total sales) × $300x) is included in DC's gross FDDEI for the taxable year.

(*11*) *Example 11: License of intangible property followed by a sale of general property that incorporates the intangible property; unrelated parties with manufacturing within the United States*—(*i*) *Facts.* The facts are the same as in paragraph (d)(2)(iv)(B)(*9*)(*i*) of this section (the facts in *Example 9*), except that FP2 manufactures its computers, tablets, smartphones, and motherboards in the United States.

(*ii*) *Analysis.* FP is not the end user or treated as an end user (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(A) of this section) because FP is not the unrelated party recipient of the general property in which the patent is embedded (the silicon chips) and the patent does not qualify as a manufacturing method or process. Under paragraph (d)(2)(ii)(A) of this section, revenue from royalties paid for the patent is earned from end users outside the United States to the extent the sale of the general property is for a foreign use under paragraph (d)(1) of this section. Because FP2 is subjecting the silicon chips to manufacture, assembly, or other processing within the United States, the revenue from royalties FP pays to DC does not qualify as foreign use based on the location of FP2's manufacturing and therefore does not qualify as a FDDEI sale. As a result, none of the $300x of annual royalties paid by FP to DC during the taxable year is included in DC's gross FDDEI for the taxable year.

(*12*) *Example 12: License of intangible property used to provide a service*—(*i*) *Facts.* DC licenses to FP worldwide rights to the copyrights on movies in exchange for an annual royalty of $100x. FP also licenses copyrights on movies from persons other than DC. FP provides a streaming service that meets the definition of an electronically supplied service in § 1.250(b)–5(c)(5) to its customers within the United States and foreign countries. FP's streaming service provides its customers a catalog of movies to choose to stream. These movies include the copyrighted movies FP licenses from DC. FP does not provide DC with data showing how much revenue FP earned from streaming services during the taxable year, even after DC requests that FP provide it with such information. DC also is unable to determine how much revenue FP earned from streaming services to customers within the United States from the data it has with respect to FP and publicly available data with respect to FP. However, DC's economic analysis of the revenue DC expected it could earn annually from use of the copyrights as part of determining the annual payments DC would receive from FP from the license of the copyrights supports a determination that $10,000x of revenue would be earned during the taxable year from customers worldwide, and that 40 percent of that revenue would be earned from customers located outside the United States. During an examination of DC's return for the taxable year, DC provides the IRS with data explaining the economic analysis, inputs, and results from its valuation of the copyrights used in determining the amount of annual payments agreed to by DC and FP.

(*ii*) *Analysis.* Under paragraph (d)(2)(ii)(B) of this section, FP's customers are the end users of the copyrights FP licenses from DC because FP uses those copyrights to provide the general service to FP's customers. Under paragraph (d)(2)(ii)(B) of this section, revenue from royalties paid for the copyrights is earned from end users outside the United States to the extent the service qualifies as a FDDEI service under § 1.250(b)–5. DC is allowed to use reliable economic analysis to estimate revenue earned by FP from streaming the licensed movies under paragraph (d)(2)(iii)(A) of this section because DC was unable to obtain actual revenue earned by FP from use of the copyrights during the taxable year after reasonable efforts to obtain the actual revenue data. Based on DC's reliable economic analysis, $40x of the annual royalty payment to DC (0.40 × $100x total annual royalty payment) is included in DC's gross FDDEI for the taxable year.

(*13*) *Example 13: License of intangible property used to in research and development of other intangible property*—(*i*) *Facts.* DC owns a patent (''patent A'') for an active pharmaceutical ingredient (''API'') approved for treatment of disease A in the United States and in foreign countries. DC licenses to FP worldwide rights to patent A for an annual royalty of $100x. FP uses patent A in research and development of a new API for treatment of disease B. Patent A does not consist of a manufacturing method or process (as defined in paragraph (d)(2)(ii)(C)(*3*) of this section). FP's research and development is successful, resulting in FP obtaining both a patent for the new API for treatment of disease B and approval for use in the United States and foreign countries. FP does not earn any revenue from

sales of finished pharmaceutical products containing the API during years 1 through 4 of the license of patent A. In year 5 of the license of patent A, FP earns $800x of revenue from sales of finished pharmaceutical products containing the API to customers located within the United States and $200x of revenue from sales to customers located in foreign countries.

(*ii*) *Analysis.* FP is not the end user (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(D) of this section) of patent A because FP is not the end user described in paragraph (d)(2)(ii)(A) of this section of the product in which the API that was developed from patent A is embedded. The unrelated party customers that purchase the finished pharmaceutical product from FP are the end users (as defined in § 1.250(b)–3(b)(2) and paragraph (d)(2)(ii)(D) of this section) because those customers are the end users described in paragraph (d)(2)(ii)(A) of this section of the pharmaceutical product in which the newly developed patent is embedded. During the taxable years that include years 1 through 4 of the license of patent A, FP earns no revenue from sales of the API to a foreign person for a foreign use. Under paragraph (d)(2)(ii)(D) of this section, none of the $100x annual royalty payments to DC for each of the tax years that include years 1 through 4 of the license of patent A is included in DC's gross FDDEI. Based on FP's sales of the API during the tax year that includes year 5 of the license of patent A, $20x of the annual royalty payment to DC ($200x of revenue from sales of API to customers located outside the United States divided by $1,000x total worldwide revenue earned from sales of the API) × $100x annual royalty) is included in DC's gross FDDEI for the taxable year.

(3) *Foreign use substantiation for certain sales of property*—(i) *In general.* Except as provided in § 1.250(b)–3(f)(3) (relating to certain loss transactions), a sale of property described in paragraphs (d)(1)(ii)(C) of this section (foreign use for sale of general property for resale), (d)(1)(iii) of this section (foreign use for sale of general property subject to manufacturing, assembly, or processing outside the United States), or (d)(2) of this section (foreign use for sale of intangible property) is a FDDEI transaction only if the taxpayer satisfies the substantiation requirements described in paragraphs (d)(3)(ii), (iii), or (iv) of this section, as applicable.

(ii) *Substantiation of foreign use for resale.* A seller satisfies the substantiation requirements with respect to a sale of property described in paragraph (d)(1)(ii)(C) of this section (sales of general property for resale) only if the seller maintains one or more of the following items—

(A) A binding contract that specifically limits subsequent sales to sales outside the United States;

(B) Proof that property is specifically designed, labeled, or adapted for a foreign market;

(C) Proof that the cost of shipping the property back to the United States relative to the value of the property makes it impractical that the property will be resold in the United States;

(D) Credible evidence obtained or created in the ordinary course of business from the recipient evidencing that property will be sold to an end user outside the United States (or, in the case of sales of fungible mass property, stating what portion of the property will be sold to end users outside the United States); or

(E) A written statement prepared by the seller containing the information described in paragraphs (d)(3)(ii)(E)(*1*) through (*7*) of this section corroborated by evidence that is credible and sufficient to support the information provided.

(*1*) The name and address of the recipient;

(*2*) The date or dates the property was shipped or delivered to the recipient;

(*3*) The amount of gross income from the sale;

(*4*) A full description of the property subject to resale;

(*5*) A description of the method of sales to the end users, such as direct sales by the recipient or sales by the recipient to retail stores;

(*6*) If known, a description of the end users; and

(*7*) A description of how the seller determined that property will be ultimately sold to an end user outside the United States (or, in the case of sales of fungible mass property, of how the taxpayer determined what portion of the property that will ultimately be sold to end users outside the United States).

(iii) *Substantiation of foreign use for manufacturing, assembly, or other processing outside the United States.* A seller satisfies the substantiation requirements with respect to a sale of property described in paragraph (d)(1)(iii) of this section (sales of general property subject to manufacturing, assembly, or other processing outside the United States) if the seller maintains one or more of the following items—

(A) Credible evidence that the property has been sold to a foreign unrelated party that is a manufacturer and such property generally cannot be sold to end users without being subject to a physical and material change (for example, the sale of raw materials that cannot be used except in a manufacturing process);

(B) Credible evidence obtained or created in the ordinary course of business from the recipient to support that the product purchased will be subject to manufacture, assembly, or other processing outside the United States within the meaning of paragraph (d)(1)(iii) of this section; or

(C) A written statement prepared by the seller containing the information described in paragraphs (d)(3)(iii)(C)(*1*) through (*7*) of this section corroborated by evidence that is credible and sufficient to support the information provided.

(*1*) The name and address of the manufacturer of the property;

(*2*) The date or dates the property was shipped or delivered to the recipient;

(*3*) The amount of gross income from the sale;

(*4*) A full description of the general property sold and the type or types of finished goods that will incorporate the general property the taxpayer sold;

(*5*) A description of the manufacturing, assembly, or other processing operations, including the location or locations of manufacture, assembly, or other processing; how the general property will be used in the finished good; and the nature of the finished good's manufacturing, assembly, or other processing operations as compared to the process used to make the general property used to make the finished good;

(*6*) A description of how the seller determined the general property was substantially transformed or the activities were substantial in nature within the meaning of paragraph (d)(1)(iii)(B) or (C) of this section, whichever the case may be; and,

(*7*) If the seller is relying on the rule described in paragraph (d)(1)(iii)(C) of this section (that the fair market value of the general property be no more than twenty percent of the fair market value when incorporated into the finished goods sold to end users), an explanation of how the seller satisfies the requirements in that paragraph.

(iv) *Substantiation of foreign use of intangible property.* A taxpayer satisfies the substantiation requirements with respect to a sale of property described in paragraph (d)(2) of this section (foreign use for intangible property) if the seller maintains one or more of the following items—

(A) A binding contract that specifically provides that the intangible property can be exploited solely outside the United States;

(B) Credible evidence obtained or created in the ordinary course of business from the recipient establishing the portion of its revenue for a taxable year that was derived from exploiting the intangible property outside the United States; or

(C) A written statement prepared by the seller containing the information described in paragraphs (d)(3)(iv)(C)(*1*)

through (*9*) of this section corroborated by evidence that is credible and sufficient to support the information provided.

(*1*) The name and address of the recipient;

(*2*) The date of the sale;

(*3*) The amount of gross income from the sale;

(*4*) A description of the intangible property;

(*5*) An explanation of how the intangible property will be used by the recipient (embedded in general property, used to provide a service, used as a manufacturing method or process, or used in research and development);

(*6*) An explanation of how the seller determined what portion of the sale is a FDDEI sale;

(*7*) If the intangible property consists of a manufacturing method or process, an explanation of how the elements of paragraph (d)(2)(ii)(C) of this section are satisfied;

(*8*) If the sale is for periodic payments, an explanation of how the seller determined the extent of foreign use based on the actual revenue earned by the recipient from the use of the intangible property for the taxable year in which a periodic payment is received as required by paragraph (d)(2)(iii)(A) of this section, or, if actual revenue cannot be obtained after reasonable efforts, an explanation of why actual revenue is unavailable and how the seller determined the extent of foreign use based on estimated revenue; and

(*9*) If the sale is for a lump sum, an explanation of how the seller determined the total net present value of revenue it expected to earn from the exploitation of the intangible property outside the United States and the total net present value of revenue it expected to earn from the exploitation of the intangible property as required by paragraph (d)(2)(iii)(B) of this section.

(v) *Examples.* The following examples illustrate the application of this paragraph (d)(3).

(A) *Assumed facts.* The following facts are assumed for purposes of the examples—

(*1*) DC is a domestic corporation.

(*2*) FP is a foreign person located within Country A that is a foreign unrelated party with respect to DC.

(*3*) All of DC's income is DEI.

(*4*) Except as otherwise provided, the substantive rule for foreign use as described in paragraphs (d)(1) and (2) of this section are satisfied.

(B) *Examples*—

(*1*) *Example 1: Substantiation by seller of sale of products to distributor outside the United States with taxpayer statement and corroborating evidence*—(*i*) *Facts.* DC sells smartphones to FP, a distributor of electronics that sells property to end users. As part of their regular business process and pursuant to DC's terms and conditions of sales, DC issues commercial invoices to FP that contain a condition that any subsequent sales must be to end users outside the United States. At or near the time of the FDII filing date, DC prepares a statement containing the information required in paragraph (d)(3)(ii)(E) of this section. During an examination of DC's return for the taxable year, the IRS requests substantiation information of foreign use. DC submits the commercial invoices issued to FP as supporting information that FP's customers are end users outside the United States and all other corroborating evidence to the IRS.

(*ii*) *Analysis.* DC's sale to FP is a sale of general property for resale subject to the substantiation requirements of paragraph (d)(3)(ii) of this section. DC satisfies the substantiation requirement by providing the statement that satisfies the requirements of paragraph (d)(3)(ii)(E) of this section. The commercial invoices issued pursuant to the terms and conditions of sales sufficiently corroborate DC's statement that the smartphones will ultimately be sold to end users outside of the United States.

(*2*) *Example 2: Substantiation of sale of products to distributor outside the United States with recipient provided information*—(*i*) *Facts.* DC sells cameras to FP, a distributor of electronics that sells property to end users outside the United States. FP issues sales invoices to its end users. The invoices contain detailed information about the nature of the subsequent sales of the cameras and the location of the end users for value added tax (VAT) purposes. DC is able to obtain copies of FP's VAT invoices with respect to the camera sales that were maintained and submitted pursuant to Country A law. Rather than prepare a statement described in paragraph (d)(3)(ii)(E) of this section, DC submits FP's invoices to the IRS as substantiation of foreign use.

(*ii*) *Analysis.* DC's sale to FP is a sale of general property for resale subject to the substantiation requirements of paragraph (d)(3)(ii) of this section. DC satisfies the substantiation requirements by providing the invoices that satisfy the requirements of paragraph (d)(3)(ii)(D) of this section. The VAT invoices issued by FP pursuant to Country A law constitute credible evidence from FP that ultimate sales are to end users located outside the United States.

(e) *Sales of interests in a disregarded entity.* Under Federal income tax principles, the sale of any interest in an entity that is disregarded for Federal income tax purposes is considered the sale of the assets of that entity, and this section applies to the sale of each such asset that is general property or intangible property for purposes of determining whether such sale qualifies as a FDDEI sale.

(f) *FDDEI sales hedging transactions*—(1) *In general.* The amount of a corporation's or partnership's gross FDDEI from FDDEI sales of general property in a taxable year is increased by any gain, or decreased by any loss, taken into account in that taxable year with respect to any FDDEI sales hedging transactions (determined by taking into account the applicable Federal income tax accounting rules, including § 1.446–4).

(2) *FDDEI sales hedging transaction*—The term *FDDEI sales hedging transaction* means a transaction that meets the requirements of § 1.1221–2(a) through (e) and that is identified in accordance with the requirements of § 1.1221–2(f), except that the transaction must manage risk of price changes or currency fluctuations with respect to ordinary property, as provided in § 1.1221–2(b)(1), and the ordinary property whose price risk is being hedged must be general property that is sold in a FDDEI sale.

§ 1.250(b)–5 Foreign-derived deduction eligible income (FDDEI) services.

(a) *Scope.* This section provides rules for determining whether a provision of a service is a FDDEI service. Paragraph (b) of this section defines a FDDEI service. Paragraph (c) of this section provides definitions relevant for determining whether a provision of a service is a FDDEI service. Paragraph (d) of this section provides rules for determining whether a general service is provided to a consumer located outside the United States. Paragraph (e) of this section provides rules for determining whether a general service is provided to a business recipient located outside the United States. Paragraph (f) of this section provides rules for determining whether a proximate service is provided to a recipient located outside the United States. Paragraph (g) of this section provides rules for determining whether a service is provided with respect to property located outside the United States. Paragraph (h) of this section provides rules for determining whether a transportation service is provided to a recipient, or with respect to property, located outside the United States.

(b) *Definition of FDDEI service.* Except as provided in § 1.250(b)–6(d), the term *FDDEI service* means a provision of a service described in any one of paragraphs (b)(1) through (5) of this section. If only a portion of a service is treated as provided to a person, or with respect to property, outside the United States, the provision of the service is a FDDEI service only to the extent of the gross income derived with respect to such portion.

(1) The provision of a general service to a consumer located outside the United States (as determined under paragraph (d) of this section).

(2) The provision of a general service to a business recipient located outside the United States (as determined under paragraph (e) of this section).

(3) The provision of a proximate service to a recipient located outside the United States (as determined under paragraph (f) of this section).

(4) The provision of a property service with respect to tangible property located outside the United States (as determined under paragraph (g) of this section).

(5) The provision of a transportation service to a recipient, or with respect to property, located outside the United States (as determined under paragraph (h) of this section).

(c) *Definitions.* This paragraph (c) provides definitions that apply for purposes of this section and § 1.250(b)–6.

(1) *Advertising service.* The term *advertising service* means a general service that consists primarily of transmitting or displaying content (including via the internet) to consumers with a purpose to generate revenue based on the promotion of a product or service.

(2) *Benefit.* The term *benefit* has the meaning set forth in § 1.482–9(l)(3).

(3) *Business recipient.* The term *business recipient* means a recipient other than a consumer and includes all related parties of the recipient. However, if the recipient is a related party of the taxpayer, the term does not include the taxpayer.

(4) *Consumer.* The term *consumer* means a recipient that is an individual that purchases a general service for personal use.

(5) *Electronically supplied service.* The term *electronically supplied service* means, with respect to a general service other than an advertising service, a service that is delivered primarily over the internet or an electronic network. Electronically supplied services include the provision of access to digitized products (such as streaming content without downloading the content); on-demand network access to computing resources, such as networks, servers, storage, and software; the provision or support of a business or personal presence on a network (such as a website or a web page); services automatically generated from a computer via the internet or other network in response to data input by the recipient; the provision of information electronically; and similar services.

(6) *General service.* The term *general service* means any service other than a property service, proximate service, or transportation service. The term *general service* includes advertising services and electronically supplied services.

(7) *Property service.* The term *property service* means a service, other than a transportation service, provided with respect to tangible property, but only if substantially all of the service is performed at the location of the property and results in physical manipulation of the property such as through manufacturing, assembly, maintenance, or repair. Substantially all of a service is performed at the location of property only if the renderer spends more than 80 percent of the time providing the service at or near the location of the property.

(8) *Proximate service.* The term *proximate service* means a service, other than a property service or a transportation service, provided to a consumer or business recipient, but only if substantially all of the service is performed in the physical presence of the consumer or, in the case of a business recipient, substantially all of the service is performed in the physical presence of persons working for the business recipient such as employees, contractors, or agents. Substantially all of a service is performed in the physical presence of a consumer or persons working for a business recipient only if the renderer spends more than 80 percent of the time providing the service in the physical presence of such persons.

(9) *Transportation service.* The term *transportation service* means a service to transport a person or property using aircraft, railroad rolling stock, vessel, motor vehicle, or any other mode of transportation. Transportation services include freight forwarding and similar services.

(d) *General services provided to consumers*—(1) *In general.* A general service is provided to a consumer located outside the United States if the consumer of a general service resides outside of the United States when the service is provided. Except as provided in paragraph (d)(2) of this section, if the renderer does not have or cannot after reasonable efforts obtain the consumer's location of residence when the service is provided, the consumer of a general service is treated as residing at the location of the consumer's billing address. However, the rule in the preceding sentence allowing for the use of a consumer's billing address does not apply if the renderer knows or has reason to know that the consumer does not reside outside the United States. A renderer has reason to know that the consumer does not reside outside the United States if the information received as part of the provision of the service indicates that the consumer resides in the United States and the renderer fails to obtain evidence establishing that the consumer resides outside the United States.

(2) *Electronically supplied services.* The consumer of an electronically supplied service is deemed to reside at the location of the device used to receive the service. Such location may be determined based on the location of the IP address when the electronically supplied service is provided. However, if the renderer does not have or cannot after reasonable efforts obtain the consumer's device location, then the location of the device is treated as being outside the United States if the renderer's billing address for the consumer is outside of the United States, subject to the knowledge and reason to know standards described in paragraph (d)(1) of this section.

(3) *Example.* The following example illustrates the application of paragraph (d) of this section.

(i) *Facts.* DC, a domestic corporation, provides a streaming movie service on its website. The terms of the service allow consumers to watch movies over the internet. The terms of the service permit the consumer to view the movies for personal use, but convey no ownership of movies to the consumers.

(ii) *Analysis.* The streaming service is a FDDEI service under paragraph (d)(1) of this section to the extent that the service is provided to consumers that reside outside the United States. The service that DC provides is a general service, provided to consumers that is an electronically supplied service under paragraph (c)(5) of this section. Therefore, the consumers are deemed to reside at the location of the devices used to receive the service under paragraph (d)(2) of this section. However, if the renderer cannot reasonably obtain the consumers' device location (such as IP addresses), the device location is treated as being outside the United States if their billing addresses are outside the United States. See § 1.250(b)–4(d)(1)(v)(B)(*7*) for an example of digital content provided to consumers as a sale rather than a service.

(e) *General services provided to business recipients*—(1) *In general.* A general service is provided to a business recipient located outside the United States to the extent that the service confers a benefit on the business recipient's operations outside the United States under the rules in paragraph (e)(2) of this section. The location of residence, incorporation, or formation of a business recipient is not relevant to determining the location of the business recipient's operations that benefit from a general service.

(2) *Determination of business operations that benefit from the service*—(i) *In general.* Except as otherwise provided in paragraph (e)(2)(ii) and (iii) of this section, the

determination of which operations of the business recipient located outside the United States benefit from a general service, and the extent to which such operations benefit, is made under the principles of § 1.482–9 by treating the taxpayer as one controlled taxpayer, the portions of the business recipient's operations within the United States (if any) that may benefit from the general service as one or more controlled taxpayers, and the portions of the business recipient's operations outside the United States (if any) that may benefit from the general service, each as one or more controlled taxpayers. The extent to which a business recipient's operations within or outside of the United States are treated as one or more separate controlled taxpayers is determined under any reasonable method (for example, separate controlled taxpayers may be determined on a per entity or per country basis, or by aggregating all of the business recipient's operations outside the United States as one controlled taxpayer). The determination of the amount of the benefit conferred on the business recipient's operations that are treated as controlled taxpayers is determined under a reasonable method consistent with the principles of § 1.482–9(k), treating the renderer's gross income from the services provided to the business recipient as if it were a ''cost'' as that term is used in § 1.482–9(k). Reasonable methods may include, for example, allocations based on time spent or costs incurred by the renderer or sales, profits, or assets of the business recipient. The determination is made when the service is provided based on information obtained from the business recipient or on the renderer's own records (such as time spent working with the business recipient's offices located outside the United States).

(ii) *Advertising services.* With respect to advertising services, the operations of the business recipient that benefit from the advertising service provided by the renderer are deemed to be located where the advertisements are viewed by individuals. If advertising services are displayed via the internet, the advertising services are viewed at the location of the device on which the advertisements are viewed. For this purpose, the IP address may be used to establish the location of a device on which an advertisement is viewed.

(iii) *Electronically supplied services.* With respect to an electronically supplied service, the operations of the business recipient that benefit from that service provided by the renderer are deemed to be located where the business recipient (including employees, contractors, or agents) accesses the service. If it cannot be determined whether the location is within or outside the United States (such as where the location of access cannot be reliably determined using the location of the IP address of the device used to receive the service), and the gross receipts from all services with respect to the business recipient are in the aggregate less than $50,000 for the renderer's taxable year, the operations of the business recipient that benefit from the service provided by the renderer are deemed to be located at the recipient's billing address; otherwise, the operations of the business recipient that benefit is deemed to be located in the United States. If the renderer provides a service that is partially an electronically supplied service and partially a general service that is not an electronically supplied service (such as a service that is performed partially online and partially by mail or in person), the location of the business recipient is determined using the rule for electronically supplied services in this paragraph (e)(2)(iii) if the primary purpose of the service is to provide electronically supplied services; otherwise, the rule for general services described in paragraph (e)(2)(i) of this section applies.

(3) *Identification of business recipient's operations*—(i) *In general.* For purposes of this paragraph (e), except with respect to advertising services and electronically supplied services, a business recipient is treated as having operations where it maintains an office or other fixed place of business. In general, an office or other fixed place of business is a fixed facility, that is, a place, site, structure, or other similar facility, through which the business recipient engages in a trade or business. For purposes of making the determination in this paragraph (e)(3)(i), the renderer may make reliable assumptions based on the information available to it.

(ii) *Advertising services and electronically supplied services.* The location of a business recipient that receives advertising services or electronically supplied services will be determined under the rules of paragraph (e)(2)(ii) and (iii) of this section, respectively, even if the business recipient does not maintain an office or other fixed place of business in the locations where the advertisements are viewed (in the case of advertising services) or where the general service is accessed (in the case of electronically supplied services).

(iii) *No office or fixed place of business.* In the case of general services other than advertising services and other than electronically supplied services, if the business recipient does not have an identifiable office or fixed place of business (including the office of a principal manager or managing owner), the business recipient is deemed to be located at its primary billing address.

(4) *Substantiation of the location of a business recipient's operations outside the United States.* Except as provided in § 1.250(b)–3(f)(3) (relating to certain loss transactions), a general service provided to a business recipient is treated as a FDDEI service only if the renderer substantiates its determination of the extent to which the service benefits a business recipient's operations outside the United States. A renderer satisfies the preceding sentence if the renderer maintains one or more of the following items—

(i) Credible evidence obtained or created in the ordinary course of business from the business recipient establishing the extent to which operations of the business recipient outside the United States benefit from the service; or

(ii) A written statement prepared by the renderer containing the information described in paragraphs (e)(4)(ii)(A) through (F) of this section corroborated by evidence that is credible and sufficient to support the information provided.

(A) The name of the business recipient;

(B) The date or dates of the service;

(C) The amount of gross income from the service;

(D) A full description of the service;

(E) A description of how the service will benefit the business recipient; and

(F) An explanation of how the renderer determined what portion of the service will benefit the business recipient's operations located outside the United States.

(5) *Examples.* The following examples illustrate the application of this paragraph (e).

(i) *Assumed facts.* The following facts are assumed for purposes of the examples—

(A) DC is a domestic corporation.

(B) A and R are not related parties of DC.

(C) Except as otherwise provided, the substantiation requirements described in paragraph (e)(4) of this section are satisfied.

(ii) *Examples*—

(A) *Example 1: Determination of business operations that benefit from the service*—(*1*) *Facts.* For the taxable year, DC provides a consulting service to R, a company that operates restaurants within and outside of

the United States, in exchange for $150x. Fifty percent of the sales earned by R and its related parties are from customers located outside of the United States. However, the consulting service that DC provides relates specifically to a single chain of fast food restaurants that R operates. Sales information that R provides to DC indicates that 70 percent of the sales of the fast food restaurant chain are from locations within the United States and 30 percent of the sales are from Country X. DC determines that the use of sales is a reasonable method under the principles of § 1.482–9(k) to allocate the benefit of the consulting service among R's fast food operations.

(*2*) *Analysis.* Under paragraph (e)(1) of this section, DC's service is provided to a person located outside the United States to the extent that DC's service confers a benefit to R's operations outside the United States. Under paragraph (e)(2)(i) of this section, DC, R's fast food operations within the United States, and R's fast food operations in Country X, are treated as if they were controlled taxpayers because only these operations may benefit from DC's service. The principles of § 1.482–9(k) apply to determine the amount of DC's service that benefits R's operations outside the United States. DC's gross income is allocated based on the sales of the fast food chain of restaurants that benefits from DC's service because using sales is a reasonable method. Therefore, 30 percent of the provision of the consulting service is treated as the provision of a service to a person located outside the United States and a FDDEI service under paragraph (b)(2) of this section. Accordingly, $45x ($150x × 0.30) of DC's gross income from the provision of the consulting service is included in DC's gross FDDEI for the taxable year.

(B) *Example 2: Determination of business operations that benefit from the service; alternative facts*—(*1*) *Facts.* The facts are the same as in paragraph (e)(5)(ii)(A)(*1*) of this section (the facts in *Example 1*), except that DC provides an information technology service to R that benefits R's entire business. DC determines that the use of sales is a reasonable method under the principles of § 1.482–9(k) to allocate the benefit of the information technology service among R's entire business.

(*2*) *Analysis.* DC, R's operations within the United States, and R's operations in Country X, are treated as if they were controlled taxpayers because the service that DC provides relates to R's entire business. DC's gross income is allocated based on sales of the entire business because using sales is a reasonable method to determine the amount of DC's service that benefits R's operations outside the United States under the principles of § 1.482–9(k). Therefore, 50 percent of the provision of the information technology service is treated as a service to a person located outside the United States and a FDDEI service under paragraph (b)(2) of this section. Accordingly, $75x ($150x × 0.50) of DC's gross income from the provision of the information technology service is included in DC's gross FDDEI for the taxable year.

(C) *Example 3: Advertising services*—(*1*) *Facts.* The facts are the same as in paragraph (e)(5)(ii)(A)(*1*) of this section (the facts in *Example 1*), except that DC provides an advertising service to R. DC displays advertisements for R's restaurant chain on its social media website and smartphone application. Based on the IP addresses of the devices on which the advertisements are viewed, 20 percent of the views of the advertisements were from devices located outside the United States.

(*2*) *Analysis.* Because the service that DC provides is an advertising service, under paragraph (e)(2)(i) of this section, as modified by paragraph (e)(2)(ii) of this section, R's operations that benefit from DC's advertising service are deemed to be where the advertisements are viewed. Therefore, 20 percent of the provision of the advertising service is treated as a service to a person located outside the United States and a FDDEI service under paragraph (b)(2) of this section. Accordingly, $30x ($150x × 0.20) of DC's gross income from the provision of the advertising service is included in DC's gross FDDEI for the taxable year.

(D) *Example 4: No reliable information about which operations benefit from the service or publicly available information*—(*1*) *Facts.* For the taxable year, DC provides a consulting service to R, a business-facing company that does not advertise its business. All of DC's interaction with R is through R's employees that report to an office in the United States. Statements made by R's employees indicate that the service will benefit R's business operations located within and outside the United States, but do not provide information that would allow DC to reliably determine the extent to which its service will confer a benefit on R's business operations located outside the United States.

(*2*) *Analysis.* DC is unable to determine the extent to which its service will confer a benefit on R's business operations located outside the United States under paragraph (e)(2)(i) of this section. Accordingly, DC cannot substantiate a determination of the extent to which the service benefits a business recipient's operations outside the United States under paragraph (e)(4) of this section. Therefore, no portion of DC's service is a FDDEI service.

(E) *Example 5: Electronically supplied services that are accessed by the business recipient's employees*—(*1*) *Facts.* DC provides payroll services for R. As part of this service, DC maintains a website through which R can enter payroll information for its employees and through which R's employees can enter and change their personal information. DC also causes R's employees' paychecks to be directly deposited into their bank accounts and pays R's employment taxes on R's behalf. The primary purpose of the service is to pay R's employees. R has 100 user accounts that access DC's website. Sixty of the user accounts that access DC's website access the website from devices that are located outside the United States and forty of the user accounts access the website from devices that are located inside the United States.

(*2*) *Analysis.* Under paragraph (e)(1) of this section, DC's service is provided to a person located outside the United States to the extent that DC's service confers a benefit to R's operations outside the United States. The service that DC provides to R is an electronically supplied service under paragraph (c)(5) of this section. Accordingly, under paragraph (e)(2)(i) of this section, as modified by paragraph (e)(2)(iii) of this section, R's operations that benefit from DC's services are deemed to be located where R accesses the service, which is where R's employees access the website. See paragraph (e)(2)(iii) of this section. Accordingly, the portion of the payroll service that is treated as a service to a person located outside the United States and a FDDEI service under paragraph (b)(2) of this section is determined based on the extent to which the locations where R accesses the website are located outside the United States. Because 60 percent (60/100) of user accounts access DC's website from locations outside the United States, 60 percent of the provision of the payroll service is treated as a service to a person located outside the United States and a FDDEI service under paragraph (b)(2) of this section.

(F) *Example 6: Electronically supplied services that are accessed by the business recipient's customers*—(*1*) *Facts.* DC maintains a website for R, a company that sells consumer goods online. R's offices are in the United States, but R sells its products to customers both within and outside the United States. Based on the IP addresses of the devices on which the website is accessed, 30 percent of the devices that accessed the website during the taxable year were located outside the United States.

(*2*) *Analysis.* Under paragraph (e)(1) of this section, DC's service is provided to a person located outside the United States to the extent that DC's service confers a benefit to R's operations outside the United States. The service that DC provides to R is an electronically supplied service under paragraph (c)(5) of this section. Accordingly, under paragraph (e)(2)(i) of this section, as modified by paragraph (e)(2)(iii) of this section, R's operations that benefit from DC's services are deemed to be located where the service is accessed, which is where R's website is accessed in this example. Therefore, 30 percent of the provision of the website maintenance service is treated as a service to a person located outside the United States and a FDDEI service under paragraph (b)(2) of this section.

(G) *Example 7: Service provided to a domestic person*—(*1*) *Facts.* A, a domestic corporation that operates solely in the United States, enters into a services agreement with R, a company that operates solely outside the United States. Under the agreement, A agrees to perform a consulting service for R. A hires DC to provide a service to A that A will use in the provision of a consulting service to R.

(*2*) *Analysis.* Because DC provides a service to A, a person located within the United States, DC's provision of the service to A is not a FDDEI service under paragraph (b)(2) of this section, even though the service is used by A in providing a service to R, a person located outside the United States. See also section 250(b)(5)(B)(ii). However, A's provision of the consulting service to R may be a FDDEI service, in which case A's gross income from the provision of such service would be included in A's gross FDDEI.

(f) *Proximate services.* A proximate service is provided to a recipient located outside the United States if the proximate service is performed outside the United States. In the case of a proximate service performed partly within the United States and partly outside of the United States, a proportionate amount of the service is treated as provided to a recipient located outside the United States corresponding to the portion of time the renderer spends providing the service outside of the United States.

(g) *Property services*—(1) *In general.* Except as provided in paragraph (g)(2) of this section, a property service is provided with respect to tangible property located outside the United States only if the property is located outside the United States for the duration of the period the service is performed.

(2) *Exception for services provided with respect to property temporarily in the United States.* A property service is deemed to be provided with respect to tangible property located outside the United States if the following conditions are satisfied—

(i) The property is temporarily in the United States for the purpose of receiving the property service;

(ii) After the completion of the service, the property will be primarily hangared, stored, or used outside the United States;

(iii) The property is not used to generate revenue in the United States at any point during the duration of the service; and

(iv) The property is owned by a foreign person that resides or primarily operates outside the United States.

(h) *Transportation services.* Except as provided in this paragraph (h), a transportation service is provided to a recipient, or with respect to property, located outside the United States only if both the origin and the destination of the service are outside of the United States. However, in the case of a transportation service provided to a recipient, or with respect to property, where either the origin or the destination of the service is outside of the United States, but not both, then 50 percent of the gross income from the transportation service is considered derived from services provided to a recipient, or with respect to property, located outside the United States.

§ 1.250(b)–6 Related party transactions.

(a) *Scope.* This section provides rules for determining whether a sale of property or a provision of a service to a related party is a FDDEI transaction. Paragraph (b) of this section provides definitions relevant for determining whether a sale of property or a provision of a service to a related party is a FDDEI transaction. Paragraph (c) of this section provides rules for determining whether a sale of general property to a foreign related party is a FDDEI sale. Paragraph (d) of this section provides rules for determining whether the provision of a general service to a business recipient that is a related party is a FDDEI service.

(b) *Definitions.* This paragraph (b) provides definitions that apply for purposes of this section.

(1) *Related party sale.* The term *related party sale* means a sale of general property to a foreign related party. See § 1.250(b)–1(e)(3)(ii)(D) (*Example 4*) for an illustration of a related party sale in the case of a seller that is a partnership.

(2) *Related party service.* The term *related party service* means a provision of a general service to a business recipient that is a related party of the renderer and that is described in § 1.250(b)–5(b)(2) without regard to paragraph (d) of this section.

(3) *Unrelated party transaction.* The term *unrelated party transaction* means, with respect to property purchased by a foreign related party (the ''purchased property'') in a related party sale from a seller—

(i) A sale of the purchased property by the foreign related party in the ordinary course of its business to a foreign unrelated party with respect to the seller;

(ii) A sale of property by the foreign related party to a foreign unrelated party with respect to the seller, if the purchased property is a constituent part of the property sold to the foreign unrelated party;

(iii) A sale of property by the foreign related party to a foreign unrelated party with respect to the seller, if the purchased property is not a constituent part of the product sold to the foreign unrelated party but rather is used in connection with producing the property sold to the foreign unrelated party; or

(iv) A provision of a service by the foreign related party to a foreign unrelated party with respect to the seller, if the purchased property was used in connection with the provision of the service.

(c) *Related party sales*—(1) *In general.* A related party sale of general property is a FDDEI sale only if the requirements described in either paragraph (c)(1)(i) or (ii) of this section are satisfied with respect to the related party sale. This paragraph (c) does not apply in determining whether a sale of intangible property to a foreign related party is a FDDEI sale.

(i) *Sale of property in an unrelated party transaction.* A related party sale is a FDDEI sale if an unrelated party transaction described in paragraph (b)(3)(i) or (ii) of this section occurs with respect to the property purchased in the related party sale and such unrelated party transaction is described in § 1.250(b)–4(b) (definition of FDDEI sale). The seller in the related party sale may establish that an unrelated party transaction will occur with respect to the property, or what portion of the property will be sold in an unrelated party transaction in the case of sale of a fungible mass of general property, based on contractual terms (including, for example, that the related party is contractually bound to only sell the product to foreign unrelated parties), past practices of the foreign related party (such as practices to only sell products to foreign unrelated parties), a showing that the product sold is designed specifically for a foreign market, or books and records otherwise evidencing that sales will be made to foreign unrelated parties.

(ii) *Use of property in an unrelated party transaction.* A related party sale is a FDDEI sale if one or more unrelated party transactions described in paragraph (b)(3)(iii) or (iv) of this section occurs with respect to the property purchased in the related party sale and such unrelated party transaction or transactions would be described in § 1.250(b)–4(b) or § 1.250(b)–5(b) (definition of FDDEI service). If the property purchased in the related party sale will be used in unrelated party transactions described in the preceding sentence and other transactions, the amount of gross income from the related party sale that is attributable to a FDDEI sale is equal to the gross income from the related party sale multiplied by a fraction, the numerator of which is the revenue that the related party reasonably expects (as of the FDII filing date) to earn from all unrelated party transactions with respect to the property purchased in the related party sale that would be described in § 1.250(b)–4(b) or § 1.250(b)–5(b) and the denominator of which is the total revenue that the related party reasonably expects (as of the FDII filing date) to earn from all transactions with respect to the property purchased in the related party sale.

(2) *Treatment of foreign related party as seller or renderer.* For purposes of determining whether a sale of property or provision of a service by a foreign related party is, or would be, described in § 1.250(b)–4(b) or § 1.250(b)–5(b), the foreign related party that sells the property or provides the service is

treated as a seller or renderer, as applicable, and the foreign unrelated party is treated as the recipient.

(3) *Transactions between related parties.* For purposes of determining whether an unrelated party sale has occurred and satisfies the requirements of paragraphs (c)(1) or (2) of this section with respect to a sale to a foreign related party (and not for purposes of determining whether a sale is to a foreign person as required by § 1.250(b)–4(b)), all related parties of the seller are treated as if they are part of a single foreign related party. For purposes of the preceding sentence, in determining whether a United States person is a member of the seller's modified affiliated group, and therefore a related party of the seller, the definition of the term *modified affiliated group* in § 1.250(b)–1(c)(17) applies without the substitution of ''more than 50 percent'' for ''at least 80 percent'' each place it appears. Accordingly, if a foreign related party sells or uses property purchased in a related party sale in a transaction with a second related party of the seller, transactions between the second related party and an unrelated party may be treated as an unrelated party transaction for purposes of applying paragraph (c)(1) of this section to a related party sale.

(4) *Example.* The following example illustrates the application of this paragraph (c).

(i) *Facts.* DC, a domestic corporation, sells a machine to FC, a foreign related party of DC in a transaction described in § 1.250(b)–4(b) (without regard to this paragraph (c)). FC uses the machine solely to manufacture product A. As of the FDII filing date for the taxable year, 75 percent of future revenue from sales by FC to unrelated parties of product A will be from sales that would be described in § 1.250(b)–4(b).

(ii) *Analysis.* The sale by DC to FC is a related party sale. Because FC uses the machine to make product A, but the machine is not a constituent part of product A because FC does not undertake further manufacturing with respect to the machine itself, FC's sale of product A is an unrelated party transaction described in paragraph (b)(3)(iii) of this section. Therefore, DC's sale of the machine is only a FDDEI sale if the requirements of paragraph (c)(1)(ii) of this section are satisfied. Because 75 percent of the revenue from future sales of product A will be from unrelated party transactions that would be described in § 1.250(b)–4(b), 75 percent of the revenues from DC's sale of the machine to FC constitute FDDEI sales.

(d) *Related party services*—(1) *In general.* Except as provided in this paragraph (d)(1), a related party service is a FDDEI service only if the related party service is not substantially similar to a service that has been provided or will be provided by the related party to a person located within the United States. However, if a related party service is substantially similar to a service provided (in whole or in part) by the related party to a person located in the United States solely by reason of paragraph (d)(2)(ii) of this section, the amount of gross income from the related party service attributable to a FDDEI service is equal to the difference between the gross income from the related party service and the amount of the price paid by persons located within the United States that is attributable to the related party service. Section 250(b)(5)(C)(ii) and this paragraph (d)(1) apply only to a general service provided to a related party that is a business recipient and are not applicable with respect to any other service provided to a related party.

(2) *Substantially similar services.* A related party service is substantially similar to a service provided by the related party to a person located within the United States only if the related party service is used by the related party in whole or part to provide a service to a person located within the United States and either—

(i) 60 percent or more of the benefits conferred by the related party service are directly used by the related party to confer benefits on consumers or business recipients located within the United States; or

(ii) 60 percent or more of the price paid by consumers or business recipients located within the United States for the service provided by the related party is attributable to the related party service.

(3) *Special rules.* For purposes of paragraph (d) of this section, the rules in paragraphs (d)(3)(i) and (ii) of this section apply.

(i) *Rules for determining the location of and price paid by recipients of a service provided by a related party.* The location of a consumer or business recipient with respect to services provided by the related party is determined under § 1.250(b)–5(d) and (e)(2), respectively, but treating the related party as the renderer. Accordingly, if the related party provides a service to a business recipient, the related party is treated as conferring benefits on a person located within the United States to the extent that the service confers a benefit on the business recipient's operations located within the United States. Similarly, for purposes of applying paragraph (d)(2)(ii) of this section with respect to business recipients, the price paid by a business recipient to the related party for services is allocated proportionally based on the locations of the business recipient that benefit from the services provided by the related party.

(ii) *Rules for allocating the benefits provided by and price paid to the renderer of a related party service.* For purposes of applying paragraph (d)(2)(i) of this section with respect to benefits that are directly used by the related party to confer benefits on its recipients, the benefits provided by the renderer to the related party are allocated to the related party's consumers or business recipients within the United States based on the proportion of benefits conferred by the related party on consumers or business recipients located within the United States. For purposes of determining the amount of the price paid by persons located within the United States that is attributable to the related party service in applying paragraph (d)(2)(ii) of this section, if the related party provides services that confer benefits on persons located within the United States and outside the United States, the price paid for the related party service by the related party to the renderer is allocated proportionally based on the benefits conferred on each location by the related party to its recipients.

(4) *Examples.* The following examples illustrate the application of this paragraph (d).

(i) *Assumed facts.* The following facts are assumed for purposes of the examples—

(A) DC is a domestic corporation.

(B) FC is a foreign corporation and a foreign related party of DC that operates solely outside the United States.

(C) The service DC provides to FC is a general service provided to a business recipient located outside the United States as described in § 1.250(b)–5(b)(2) without regard to the application of paragraph (d) of this section.

(D) The benefits conferred by DC's service to FC's customers are not indirect or remote within the meaning of § 1.482–9(l)(3)(ii).

(ii) *Examples*—

(A) *Example 1: Services that are substantially similar services under paragraph (d)(2)(i) of this section*—(*1*) *Facts.* FC enters into a services agreement with R, a company that operates restaurant chains within and outside the United States. Under the agreement, FC agrees to furnish a design for the renovation of a chain of restaurants that R owns; the design will include architectural plans. FC hires DC to provide an architectural service to FC that FC will use in the provision of its design service to R. The architectural service that DC provides to FC will serve no other purpose than to enable FC to provide its service to R. The service that FC provides will benefit only R's operations within the United States. FC pays an arm's length price of $50x to DC for the

architectural service and DC recognizes $50x of gross income from the service. FC incurs additional costs to add additional design elements to the plans and charges R a total of $100x for its service.

(*2*) *Analysis.* All of the service that DC provides to FC is directly used in the provision of a service to R because FC uses DC's architectural service to provide its design service to R, and the architectural service that DC provides to FC will serve no purpose other than to enable FC to provide its service to R. In addition, FC is treated as conferring benefits only to persons located within the United States under paragraph (d)(3)(i) of this section because only R's operations within the United States benefit from the service provided by FC that used the service provided by DC. Therefore, the service provided by DC to FC is substantially similar to the service provided by FC to R under paragraph (d)(2)(i) of this section. Accordingly, DC's provision of the architectural service to FC is not a FDDEI service under paragraph (d)(1) of this section, and DC's gross income from the architectural service ($50x) is not included in its gross FDDEI.

(B) *Example 2: Services that are not substantially similar services under paragraph (d)(2)(i) of this section*—(*1*) *Facts.* The facts are the same as paragraph (d)(4)(ii)(A)(*1*) of this section (the facts in *Example 1*), except that 90 percent of R's operations that will benefit from FC's service are located outside the United States.

(*2*) *Analysis*—(*i*) *Analysis under paragraph (d)(2)(i) of this section.* All of the service that DC provides to FC is directly used in the provision of a service to R. However, because 90 percent of R's operations that will benefit from FC's service are located outside the United States under paragraph (d)(3)(i) of this section, only 10 percent of the benefits of FC's service are conferred on person's located within the United States. Further, because FC's service confers a benefit on R's operations located within and outside the United States, the benefit provided by DC to FC is allocated proportionately based on the locations of R that benefit from the services provided by FC under paragraph (d)(3)(ii) of this section. Therefore, only 10 percent of DC's architectural service are directly used by FC to confer benefits on persons located within the United States under paragraph (d)(3)(ii) of this section. Therefore, the architectural service provided by DC to FC is not substantially similar to the design service provided by FC to persons located within the United States under paragraph (d)(2)(i) of this section.

(C) *Example 3: Services that are substantially similar services under paragraph (d)(2)(ii) of this section*—(*1*) *Facts.* The facts are the same as paragraph (d)(4)(ii)(B)(*1*) of this section (the facts in *Example 2*), except that FC pays an arm's length price of $75x to DC for the architectural service and DC recognizes $75x of gross income from the service. As in paragraph (d)(4)(ii)(A)(*1*) and (d)(4)(ii)(B)(*1*) of this section (the facts in *Example 1* and *Example 2*), FC charges R a total of $100x for its service.

(*2*) *Analysis*—(*i*) *Price paid by persons located within the United States.* Under paragraph (d)(3)(i) of this section, FC is treated as conferring benefits on a person located within the United States to the extent that R's operations that will benefit from FC's service are located within the United States. Further, because FC's service confers a benefit on R's operations located within and outside the United States, the price paid by R to FC ($100x) is allocated proportionately based on the locations of R that benefit from the services provided by FC under paragraph (d)(3)(i) of this section. Accordingly, because 10 percent of the R's operations that will benefit from FC's services are located within the United States, persons located within the United States are treated as paying $10x ($100x x 0.10) for FC's services for purposes of applying the test in paragraph (d)(2)(ii) of this section.

(*ii*) *Amount attributable to the related party service.* The service that FC provides to R is attributable in part to DC's service because FC uses the architectural plans that DC provides to provide a service to R. Under paragraph (d)(3)(ii) of this section, because the benefits of the service provided by FC are conferred on persons located within the United States and outside the United States, a proportionate amount (10 percent) of the price paid to DC for the related party service ($75x), or $7.5x, is treated as attributable to the services provided to persons located within the United States.

(*iii*) *Application of test in paragraph (d)(2)(ii) of this section.* For purposes of applying the test described in paragraph (d)(2)(ii) of this section, the price paid by persons located within the United States for the service provided by the related party (FC) is $10x, as determined in paragraph (d)(4)(ii)(C)(*2*)(*i*) of this section (the analysis of this *Example 3*). The amount of the price that is attributable to DC's service is $7.5x, as determined in paragraph (d)(4)(ii)(C)(*2*)(*ii*) of this section (the analysis of this *Example 3*). Accordingly, of the price treated as paid to FC by persons located within the United States, 75 percent ($7.5x/$10x) is attributable to the related party service. Because more than 60 percent of the price treated as paid by persons within the United States for FC's service is attributable to DC's service, the service provided by DC to FC is substantially similar to the design service provided by FC to persons located within the United States under paragraph (d)(2)(ii) of this section.

(*iv*) *Conclusion.* Under paragraph (d)(1) of this section, because the related party service provided by DC is substantially similar to the service provided by FC to a person located in the United States solely by reason of paragraph (d)(2)(ii) of this section, the difference between DC's gross income from the related party service and the amount of the price paid by persons located within the United States that is attributable to the related party service is treated as a FDDEI service. Accordingly, $67.5x ($75x—$7.5x) of DC's gross income from the provision of the service to FC is treated as a FDDEI service.

■ **Par. 3.** Section 1.861–8 is amended by revising the last sentence of paragraph (d)(2)(ii)(C)(*1*) and adding paragraph (f)(1)(vi)(N) as follows:

§ 1.861–8 Computation of taxable income from sources within the United States and from other sources and activities.

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(C) * * *

(*1*) * * * The term *gross foreign-derived deduction eligible income,* or *gross FDDEI,* has the meaning provided in § 1.250(b)–1(c)(16).

* * * * *

(f) * * *

(1) * * *

(vi) * * *

(N) Deduction eligible income and foreign-derived deduction eligible income under section 250(b).

* * * * *

■ **Par. 4.** Section 1.962–1 is amended by:

■ 1. Revising paragraph (a)(2).

■ 2. Adding paragraphs (b)(1)(i)(A)(*2*) and (b)(1)(i)(B)(*3*).

■ 3. Removing and reserving paragraph (b)(1)(ii).

■ 4. Revising paragraphs (b)(2)(i) through (iii), (c), and (d)

The revisions and additions read as follows:

§ 1.962–1 Limitation of tax for individuals on amounts included in gross income under section 951(a).

(a) * * *

(2) For purposes of applying sections 960(a) and 960(d) (relating to foreign tax credit) such amounts shall be treated as if received by a domestic corporation (as provided in paragraph (b)(2) of this section).

* * * * *

(b) * * *

(1) * * *

(i) * * *

(A) * * *

(*2*) His GILTI inclusion amount (as defined in § 1.951A–1(c)(1)) for the taxable year; plus

* * * * *

(B) * * *

(*3*) The portion of the deduction under section 250 and § 1.250(a)–1 that would be allowed to a domestic corporation equal to the percentage applicable to global intangible low-taxed income for the taxable year under section 250(a)(1)(B) (including as modified by section 250(a)(3)(B)) multiplied by the sum of the amount described in paragraph (b)(1)(i)(A)(*2*) of this section and the amount described in paragraph (b)(1)(i)(A)(*3*) of this section that is attributable to the amount described in paragraph (b)(1)(i)(A)(*2*) of this section.

* * * * *

(2) * * *

(i) *In general.* Subject to the applicable limitation of section 904 and to the provisions of this paragraph (b)(2), there shall be allowed as a credit against the United States tax on the amounts described in paragraph (b)(1)(i) of this section the foreign income, war profits, and excess profits taxes deemed paid under section 960(a) or section 960(d) by the electing United States shareholder with respect to such amounts.

(ii) *Application of sections 960(a) and 960(d).* In applying sections 960(a) and 960(d) for purposes of this paragraph (b)(2) in the case of an electing United States shareholder, the term ''domestic corporation'' as used in sections 960(a), 960(d), and 78, and the term ''corporation'' as used in sections 901 and 960(d)(2)(A) and (B), are treated as referring to such shareholder with respect to the amounts described in paragraph (b)(1)(i) of this section.

(iii) *Carryback and carryover of excess tax deemed paid.* For purposes of this paragraph (b)(2), other than with respect to section 951A category income (as defined in § 1.904–4(g)) (including section 951A category income that is reassigned to a separate category for income resourced under a treaty), any amount by which the foreign income, war profits, and excess profits taxes deemed paid by the electing United States shareholder for any taxable year under section 960 exceed the limitation determined under paragraph (b)(2)(iv)(A) of this section is treated as a carryback and carryover of excess tax paid under section 904(c), except that in no case will excess tax paid be deemed paid in another taxable year under section 904(c) if an election under section 962 by the shareholder does not apply for such taxable year. Such carrybacks and carryovers are applied only against the United States tax on amounts described in paragraph (b)(1)(i) of this section.

* * * * *

(c) *Example.* The application of this section may be illustrated by the following example.

(1) *Facts*—(i) Individual A is a U.S. resident who owns all of the shares of the one class of stock in CFC, a controlled foreign corporation. A and CFC each use the calendar year as their U.S. and foreign taxable years and the U.S. dollar as their functional currency. A owns no direct or indirect interest in any other controlled foreign corporation.

(ii) For the 2019 taxable year, CFC has $6,000,000 of pre-foreign tax earnings with respect to which it accrues and pays $1,000,000 of foreign income tax, leaving $5,000,000 of after-tax net income. Of this amount, $3,000,000 is general category tested income as defined in section 951A(c)(2), and $2,000,000 is passive category subpart F income described in sections 952 and 904(d)(1)(C) that is all in a single subpart F income group under §§ 1.954–1(c)(1)(iii) and 1.960–1(d)(2)(ii)(B)(*2*)(*i*). Of the $1,000,000 of foreign income taxes paid or accrued by CFC, $600,000 is allocated and apportioned to its general category tested income group and $400,000 is allocated and apportioned to its passive category subpart F income group under § 1.960–1(d)(3)(ii).

(iii) For the 2019 taxable year, A includes under section 951A(a) all $3,000,000 of the tested income of CFC as A's GILTI inclusion amount, as defined in § 1.951A–1(c)(1). In addition, A includes under section 951(a)(1) the $2,000,000 of passive category subpart F income of CFC.

(iv) For the 2019 taxable year, A earns $1,000,000 of foreign source passive category gross income and $3,000,000 of U.S. source gross income. A pays $100,000 of foreign withholding taxes with respect to the $1,000,000 of foreign source passive category gross income. A incurs $1,000,000 of deductible expenses for the 2019 taxable year that are definitely related to all of A's gross income and are properly allocated and apportioned under §§ 1.861–8(b)(5) and 1.861–8T(c)(1) among the section 904 statutory and residual groupings on the basis of the relative amounts of gross income in each grouping.

(v) A elects to apply section 962 and chooses to claim credits under section 901 for the 2019 taxable year.

(2) *Analysis with respect to section 962 taxable income*—(i) Section 962(a)(1) and § 1.962–1(a)(1) provide that when an individual United States shareholder elects to apply section 962 for a taxable year, the U.S. tax imposed with respect to amounts that the individual includes under section 951(a) (the ''section 951(a) inclusions'') equals the tax that would be imposed under section 11 if the amounts were included by a domestic corporation under section 951(a). For purposes of section 962, an amount included under section 951A is treated as an inclusion under section 951(a). See section 951A(f)(1)(A). Therefore, A has total section 951(a) inclusions of $5,000,000: a $2,000,000 passive category subpart F inclusion and a $3,000,000 GILTI inclusion amount. A is taxed at the corporate rates under section 11 with respect to these inclusions.

(ii) Section 962(a)(2), § 1.962–1(a)(2), and § 1.962–1(b)(2) provide that sections 960(a) and 960(d) apply to the section 951(a) inclusions of an electing individual United States shareholder as though the inclusions were received by a domestic corporation, and the electing individual United States shareholder is allowed a credit against the U.S. tax imposed with respect to the section 951(a) inclusions.

(iii) Section 960(a) deems a domestic corporation that is a United States shareholder of a controlled foreign corporation to pay the foreign income taxes paid or accrued by the foreign corporation that are properly attributable to the foreign corporation's items of income included in the domestic corporation's income under section 951(a). The foreign income taxes of a CFC that are properly attributable to such items are the domestic corporation's proportionate share of the taxes that are allocated and apportioned to the relevant subpart F income group. See § 1.960–1(c) and § 1.960–2(b). A owns 100 percent of CFC, and includes all of its subpart F income, which is in a single subpart F income group. Therefore, all of the $400,000 of foreign income taxes that are allocable to CFC's subpart F income are properly attributable to the section 951(a) inclusion of A, and A is deemed to pay these taxes.

(iv) Section 960(d) provides that a domestic corporation that has an inclusion in income under section 951A is deemed to pay an amount of foreign income taxes equal to 80 percent of the product of the domestic corporation's inclusion percentage multiplied by the sum of all tested foreign income taxes. Tested foreign income taxes are the foreign income taxes of a controlled foreign corporation that are properly attributable to its tested income that the domestic corporation takes into account under section 951A. The foreign income taxes that are properly attributable to the tested income taken into account by a domestic corporation are the domestic corporation's proportionate share of the controlled foreign corporation's foreign income taxes that are allocated and apportioned to the relevant tested income. See § 1.960–1(c) and § 1.960–2(c). Because A owns 100% of CFC and takes all $3,000,000 of CFC's tested income into account in computing A's GILTI inclusion amount, all $600,000 of the foreign income taxes that are allocated and apportioned to the general category tested income group of CFC are tested foreign income taxes. A has an inclusion percentage of 100 percent because A's GILTI inclusion amount equals all of A's share of the tested income of CFC. A is therefore deemed to pay under section 960(d) 80 percent of the $600,000 of tested foreign income taxes of CFC, or $480,000 of the tested foreign income taxes.

(v) Section 1.962–1(b)(1)(i)(A) provides that, for purposes of computing taxable income under section 962, gross income includes amounts that would be included under section 78 if the shareholder with the section 951(a) inclusions were a domestic corporation. Section 78 requires a domestic corporation to include in its gross income the foreign income taxes that it is deemed to pay under section 960, computed without regard to the 80 percent limitation under section 960(d), and to which the benefits of section 901 apply. See section 78. A therefore includes in gross income the $600,000 of foreign income taxes that A is deemed to pay under section 960(d), computed without regard to the 80 percent limitation, and the $400,000 of taxes that A is deemed to pay under section 960(a).

(vi) Section 1.962–1(b)(1)(i)(B)(*3*) provides that, for purposes of computing taxable income under section 962, gross income is reduced only by specified deductions, which include the deduction allowed to a domestic corporation under section 250 and § 1.250(a)–1 equal to 50 percent of the sum of the GILTI inclusion amount and the

inclusion under section 78 with respect to the GILTI inclusion amount. See section 250(a). A is therefore allowed a deduction under section 250 equal to 50 percent of $3,600,000 (the $3,000,000 GILTI inclusion amount plus the $600,000 inclusion under section 78), or $1,800,000.

(vii) A's taxable income and pre-credit U.S. tax liability with respect to the section 951(a) inclusions are computed as follows:

TABLE 1 TO PARAGRAPH (c)(2)(vii)

Section 951(a) inclusions with respect to CFC	$5,000,000
Section 78 inclusions	1,000,000
Deduction under section 250	(1,800,000)
Taxable income under section 962	4,200,000
Pre-credit U.S. tax (0.21 × $4,200,000)	882,000

(viii) Section 962 and § 1.962–1(b)(2) provide that, in computing the section 904 limitation on the credit for foreign income taxes that an electing individual United States shareholder is deemed to pay under sections 960(a) and (d), the individual's taxable income for a taxable year is considered to consist only of section 951(a) inclusions and the deductions allowed under section 962. Section 904 limits the credit that a taxpayer may claim for the taxes that it pays or accrues, or is deemed to pay, to the amount of its U.S. tax that is attributable to the taxpayer's foreign source income, and applies this limitation separately with respect to each separate category of income. The limitation amount is computed by multiplying the taxpayer's total pre-credit U.S. tax by the ratio of the taxpayer's foreign source taxable income in a separate category for the taxable year to the taxpayer's total taxable income for the taxable year. See section 904(a) and § 1.904–1(a).

(ix) A must compute the limitation on the credit for the foreign income taxes deemed paid under section 960(d) separately with respect to A's taxable income in the separate category described in section 904(d)(1)(A) (the ''GILTI category''), namely, taxable income attributable to the GILTI inclusion amount. The limitation is computed using only A's 2019 taxable income under section 962 and the pre-credit U.S. tax of $882,000 on this income. A therefore computes the limitation by multiplying $882,000 by the ratio of A's foreign source GILTI category taxable income under section 962 to A's total taxable income under section 962, as follows:

TABLE 2 TO PARAGRAPH (c)(2)(ix)

GILTI inclusion amount	$3,000,000
Section 78 inclusion	$600,000
Section 250 deduction	($1,800,000)
Total GILTI category taxable income under section 962	$1,800,000
Ratio of GILTI category taxable income to total taxable income under section 962 (1,800,000/$4,200,000)	42.86%
Limitation amount (pre-credit U.S. tax of $882,000 × ($1,800,000/$4,200,000))	$378,000

(x) A also must compute the limitation on the credit for the foreign income taxes deemed paid under section 960(a) separately with respect to the foreign source passive category taxable income under section 962, namely, A's taxable income attributable to the subpart F inclusion. A computes the limitation by multiplying A's pre-credit U.S. tax of $882,000 by the ratio of A's foreign source passive category taxable income under section 962 to A's total taxable income under section 962, as follows:

TABLE 3 TO PARAGRAPH (c)(2)(x)

Subpart F inclusion	$2,000,000
Section 78 inclusion	$400,000
Total foreign source passive category taxable income	$2,400,000
Ratio of foreign source passive category taxable income to total taxable income under section 962 ($2,400,000/$4,200,000)	57.14%
Limitation amount (pre-credit U.S. tax of $882,000 × ($2,400,000/$4,200,000))	$504,000

(xi) A may claim a foreign tax credit for $378,000 of the $480,000 of foreign income taxes deemed paid under section 960(d), and a foreign tax credit for all $400,000 of the foreign income taxes deemed paid under section 960(a), for a total foreign tax credit of $778,000. The U.S. tax on A's 2019 taxable income with respect to CFC under section 962 is reduced from $882,000 to $104,000 ($882,000 minus $778,000).

(3) *Analysis with respect to other income*—(i) A's taxable income and pre-credit U.S. tax liability with respect to A's other income is computed as follows:

TABLE 4 TO PARAGRAPH (c)(3)(i)

Gross income	$4,000,000
Deductions	1,000,000
Taxable Income	3,000,000
Pre-credit U.S. tax computed under section 1(j)	1,074,988

(ii) A must compute a separate limitation on the credit for the foreign withholding taxes paid with respect to A's other foreign source passive category taxable income. Under § 1.962–1(b)(2)(iv)(B), A's section 904 limitation on this income is computed on the basis of A's taxable income other than the amounts taken into account under § 1.962–1(b)(1)(i). Accordingly, $250,000 of A's deductions ($1,000,000 × $1,000,000/$4,000,000) are apportioned to A's $1,000,000 of other foreign source passive category gross income, and $750,000 of deductions ($1,000,000 × $3,000,000/$4,000,000) are apportioned to A's $3,000,000 of U.S. source gross income, resulting in $750,000 of other foreign source passive category taxable income and $2,250,000 of U.S. source taxable income A computes the limitation by multiplying A's pre-credit U.S. tax on A's other income of

$1,074,988 by the ratio of A's other foreign source passive category taxable income to A's other total taxable income, as follows:

TABLE 5 TO PARAGRAPH (c)(3)(ii)

Total other foreign source passive category taxable income	$750,000
Ratio of other foreign source passive category taxable income to total other taxable income ($750,000/$3,000,000)	25%
Limitation amount (pre-credit U.S. tax of $1,074,988 × ($750,000/$3,000,000))	$268,747

(iii) A may claim a foreign tax credit under section 901 for all $100,000 of the foreign withholding taxes on the other passive income. The U.S. tax on A's $3,000,000 of other taxable income is reduced from $1,074,988 to $974,988 ($1,074,88 minus $100,000).

(d) *Applicability dates.* Except as otherwise provided in this paragraph (d), paragraph (b)(1)(i) of this section applies beginning the last taxable year of a foreign corporation that begins before January 1, 2018, and with respect to a United States person, for the taxable year in which or with which such taxable year of the foreign corporation ends. Paragraphs (b)(1)(i)(A)(*2*) and (b)(1)(i)(B)(*3*) of this section apply to taxable years of a foreign corporation that end on or after March 4, 2019, and with respect to a United States person, for the taxable year in which or with which such taxable year of the foreign corporation ends. Paragraphs (a)(2), (b)(1)(ii), (b)(2)(i) through (iii), and (c) of this section apply to taxable years of a foreign corporation that end on or after July 15, 2020, and with respect to a United States person, for the taxable year in which or with which such taxable year of the foreign corporation ends. For taxable years that precede the applicability dates described in the preceding two sentences, taxpayers may choose to apply the provisions of paragraphs (a)(2), (b)(1)(i)(A)(*2*), (b)(1)(i)(B)(*3*), (b)(1)(ii), (b)(2)(i) through (iii), and (c) of this section for taxable years of a foreign corporation beginning on or after January 1, 2018, and with respect to a United States person, for the taxable year in which or with which such taxable year of the foreign corporation ends.

■ **Par. 5.** Section 1.1502–12 is amended by adding paragraph (t) to read as follows:

§ 1.1502–12 Separate taxable income.

* * * * *

(t) See § 1.1502–50 for rules relating to the computation of a member's deduction under section 250.

* * * * *

■ **Par. 6.** Section 1.1502–13 is amended by:

■ 1. In paragraph (a)(6)(ii), under the heading ''Matching rule. (§ 1.1502–13(c)(7)(ii))'', designating *Examples 1* through *17* as entries (A) through (Q).

■ 2. In paragraph (a)(6)(ii), under the heading ''Matching rule. (§ 1.1502–13(c)(7)(ii))'', adding entry (R).

■ 3. In paragraph (c)(7)(ii), *Examples 1* through *17* are designated as paragraphs (c)(7)(ii)(A) through (Q), respectively.

■ 4. Redesignating newly designated paragraphs (c)(7)(ii)(A)(a) through (i) as paragraphs (c)(7)(ii)(A)(*1)* through (*9*).

■ 5. Redesignating newly designated paragraphs (c)(7)(ii)(B)(a) and (b) as paragraphs (c)(7)(ii)(B)(*1*) and (*2*).

■ 6. Redesignating newly designated paragraphs (c)(7)(ii)(C)(a) through (d) as paragraphs (c)(7)(ii)(C)(*1*) through (*4*).

■ 7. Redesignating newly designated paragraphs (c)(7)(ii)(D)(a) through (e) as paragraphs (c)(7)(ii)(D)(*1*) through (*5*).

■ 8. Redesignating newly designated paragraphs (c)(7)(ii)(E)(a) through (f) as paragraphs (c)(7)(ii)(E)(*1*) through (*6*).

■ 9. Redesignating newly designated paragraphs (c)(7)(ii)(F)(a) through (d) as paragraphs (c)(7)(ii)(F)(*1*) through (*4*).

■ 10. Redesignating newly designated paragraphs (c)(7)(ii)(G)(a) through (d) as paragraphs (c)(7)(ii)(G)(*1*) through (*4*).

■ 11. Redesignating newly designated paragraphs (c)(7)(ii)(I)(a) through (e) as paragraphs (c)(7)(ii)(I)(*1*) through (*5*).

■ 12. Redesignating newly designated paragraphs (c)(7)(ii)(J)(a) through (d) as paragraphs (c)(7)(ii)(J)(*1*) through (*4*).

■ 13. Redesignating newly designated paragraphs (c)(7)(ii)(K)(a) through (d) as paragraphs (c)(7)(ii)(K)(*1*) through (*4*).

■ 14. Redesignating newly designated paragraphs (c)(7)(ii)(L)(a) and (b) as paragraphs (c)(7)(ii)(L)(*1*) and (*2*).

■ 15. Redesignating newly designated paragraphs (c)(7)(ii)(N)(a) through (c) as paragraphs (c)(7)(ii)(N)(*1*) through (*3*).

■ 16. Redesignating newly designated paragraphs (c)(7)(ii)(O)(a) through (d) as paragraphs (c)(7)(ii)(O)(*1*) through (*4*).

■ 17. Redesignating newly designated paragraphs (c)(7)(ii)(P)(a) and (b) as paragraphs (c)(7)(ii)(P)(*1*) and (*2*).

■ 18. Redesignating newly designated paragraphs (c)(7)(ii)(Q)(a) through (c) as paragraphs (c)(7)(Q)(*1*) through (*3*).

■ 19. In the table in this paragraph, for each newly redesignated paragraph listed in the ''Paragraph'' column, remove the text indicated in the ''Remove'' column and add in its place the text indicated in the ''Add'' column:

Paragraph	Remove	Add
(c)(7)(ii)(A)(*5*)	paragraph (a) of this *Example 1*	*Example 1* in paragraph (c)(7)(ii)(A)(*1*) of this section.
(c)(7)(ii)(A)(*5*)	paragraphs (c) and (d) of this *Example 1*	*Example 1* in paragraphs (c)(7)(ii)(A)(*3*) and (*4*) of this section.
(c)(7)(ii)(A)(*6*)	paragraph (a) of this *Example 1*	*Example 1* in paragraph (c)(7)(ii)(A)(*1*) of this section.
(c)(7)(ii)(A)(*7*)	paragraph (a) of this *Example 1*	*Example 1* in paragraph (c)(7)(ii)(A)(*1*) of this section.
(c)(7)(ii)(A)(*8*)	paragraph (a) of this *Example 1*	*Example 1* in paragraph (c)(7)(ii)(A)(*1*) of this section.
(c)(7)(ii)(A)(*9*)	paragraph (a) of this *Example 1*	*Example 1* in paragraph (c)(7)(ii)(A)(*1*) of this section.
(c)(7)(ii)(C)(*3*)	paragraph (a) of this *Example 3*	*Example 3* in paragraph (c)(7)(ii)(C)(*1*) of this section.
(c)(7)(ii)(C)(*4*)	paragraph (c) of this *Example 3*	*Example 3* in paragraph (c)(7)(ii)(C)(*3*) of this section.
(c)(7)(ii)(C)(*4*)	paragraph (b) of this *Example 3*	*Example 3* in paragraph (c)(7)(ii)(C)(*2*) of this section.
(c)(7)(ii)(D)(*5*)	paragraph (a) of this *Example 4*	*Example 4* in paragraph (c)(7)(ii)(D)(*1*) of this section.
(c)(7)(ii)(D)(*5*)	paragraphs (c) and (d) of this *Example 4*	*Example 4* in paragraphs (c)(7)(ii)(D)(*3*) and (*4*) of this section.
(c)(7)(ii)(E)(*3*)	paragraph (a) of this *Example 5*	*Example 5* in paragraph (c)(7)(ii)(E)(*1*) of this section.
(c)(7)(ii)(E)(*4*)	paragraph (a) of this *Example 5*	*Example 5* in paragraph (c)(7)(ii)(E)(*1*) of this section.
(c)(7)(ii)(E)(*5*)	paragraph (a) of this *Example 5*	*Example 5* in paragraph (c)(7)(ii)(E)(*1*) of this section.
(c)(7)(ii)(E)(*6*)	paragraph (a) of this *Example 5*	*Example 5* in paragraph (c)(7)(ii)(E)(*1*) of this section.
(c)(7)(ii)(F)(*3*)	paragraph (a) of this *Example 6*	*Example 6* in paragraph (c)(7)(ii)(F)(*1*) of this section.
(c)(7)(ii)(F)(*4*)	paragraph (a) of this *Example 6*	*Example 6* in paragraph (c)(7)(ii)(F)(*1*) of this section.
(c)(7)(ii)(G)(*4*)	paragraph (a) of this *Example 7*	*Example 7* in paragraph (c)(7)(ii)(G)(*1*) of this section.

Paragraph	Remove	Add
(c)(7)(ii)(G)(*4*)	paragraph (c) of this *Example 7*	*Example 7* in paragraph (c)(7)(ii)(G)(*3*) of this section.
(c)(7)(ii)(I)(*3*)	paragraph (a) of this *Example 9*	*Example 9* in paragraph (c)(7)(ii)(I)(*1*) of this section.
(c)(7)(ii)(I)(*4*)	paragraph (a) of this *Example 9*	*Example 9* in paragraph (c)(7)(ii)(I)(*1*) of this section.
(c)(7)(ii)(I)(*5*)	paragraph (d) of this *Example 9*	*Example 9* in paragraph (c)(7)(ii)(I)(*4*) of this section.
(c)(7)(ii)(J)(*3*)	paragraph (a) of this *Example 10*	*Example 10* in paragraph (c)(7)(ii)(J)(*1*) of this section.
(c)(7)(ii)(J)(*4*)	paragraph (a) of this *Example 10*	*Example 10* in paragraph (c)(7)(ii)(J)(*1*) of this section.
(c)(7)(ii)(K)(*4*)	paragraph (a) of this *Example 11*	*Example 11* in paragraph (c)(7)(ii)(K)(*1*) of this section.
(c)(7)(ii)(N)(*2*)	paragraph (a) of this *Example 14*	*Example 14* in paragraph (c)(7)(ii)(N)(*1*) of this section.
(c)(7)(ii)(O)(*4*)	paragraph (a) of this *Example 15*	*Example 15* in paragraph (c)(7)(ii)(O)(*1*) of this section.
(c)(7)(ii)(Q)(*1*)	*Example 16*	*Example 16* in paragraph (c)(7)(ii)(P) of this section.
(c)(7)(ii)(Q)(*2*)	paragraph (f)(7), *Example 2* of this section	*Example 2* in paragraph (f)(7) of this section.
(c)(7)(iii)(A)	Paragraphs (c)(6)(ii)(C), (c)(6)(ii)(D), and (c)(7)(ii), *Examples 16* and *17* of this section.	Paragraphs (c)(6)(ii)(C) and (D) of this section, *Example 16* in paragraph (c)(7)(ii)(P) of this section, and *Example 17* in paragraph (c)(7)(ii)(Q) of this section.

■ 20. Adding paragraph (c)(7)(ii)(R). The additions read as follows:

§ 1.1502–13 Intercompany transactions.

(a) * * *

(6) * * *

(ii) * * *

Matching rule. (§ 1.1502–13(c)(7)(ii))

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(R) Example 18. Redetermination of attributes for section 250 purposes.

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(c) * * *

(7) * * *

(ii) * * *

(R) *Example 18: Redetermination of attributes for section 250 purposes*—(*1*) *Facts.* S manufactures equipment in the United States and recognizes $75 of gross income included in gross DEI (as defined in § 1.250(b)–1(c)(15)) on the sale of Asset, which is not depreciable property, to B in Year 1 for $100. In Year 2, B sells Asset to X for $125 and recognizes $25 of gross income. The sale is a FDDEI sale (as defined in § 1.250(b)–1(c)(8)), and thus the $25 of income is included in B's gross FDDEI (as defined in § 1.250(b)–1(c)(16)) for Year 2.

(*2*) *Timing and attributes.* S's $75 of intercompany income is taken into account in Year 2 under the matching rule to reflect the $75 difference between B's $25 corresponding item taken into account (based on B's $100 cost basis in Asset) and the recomputed corresponding item (based on the $25 basis that B would have if S and B were divisions of a single corporation and B's basis were determined by reference to S's basis). In determining whether S's gross income included in gross DEI from the sale of Asset is included in gross FDDEI, S and B are treated as divisions of a single corporation. See paragraph (a)(6) of this section. In determining the amount of income included in gross DEI that is included in gross FDDEI, the attributes of S's intercompany item and B's corresponding item may be redetermined to the extent necessary to produce the same effect on consolidated taxable income (and consolidated tax liability) as if S and B were divisions of a single corporation. See paragraph (c)(1)(i) of this section. Applying section 250 and § 1.1502–50 on a single entity basis, all $100 of income included in gross DEI would be gross FDDEI. On a separate entity basis, S would have $75 of gross income included in gross DEI that is included in gross RDEI (as defined in § 1.250(b)–1(c)(14)) and B would have $25 of gross income included in gross DEI that is included in gross FDDEI. Thus, on a separate entity basis, S and B would have, in the aggregate, $100 of gross income included in gross DEI, of which only $25 is included gross FDDEI. Accordingly, under single entity treatment, $75 that would be treated as gross income included in gross DEI that is included in gross RDEI on a separate entity basis is redetermined to be included in gross FDDEI.

(*3*) *Intercompany sale for loss.* The facts are the same as in paragraph (c)(7)(ii)(R)(*1*) of this section (the facts in *Example 18*), except that S recognizes $25 of loss on the sale of Asset. S's $25 of intercompany loss is taken into account under the matching rule to reflect the $25 difference between B's $25 corresponding item taken into account (based on B's $100 cost basis in Asset) and the recomputed corresponding item (based on the $125 basis that B would have if S and B were divisions of a single corporation and B's basis were determined by reference to S's $125 of costs). Applying section 250 and § 1.1502–50 on a single entity basis, $0 of income would be included in gross DEI. In order to reflect this result, under the matching rule, S's $25 loss is allocated and apportioned solely to B's $25 of gross income from the sale of Asset for purposes of determining B's DEI and FDDEI. Furthermore, B's $25 of gross income is not taken into account for purposes of apportioning any other deductions under section 861 and the regulations under that section for purposes of determining any member's DEI or FDDEI.

* * * * *

■ **Par. 7.** Section 1.1502–50 is added to read as follows:

§ 1.1502–50 Consolidated section 250.

(a) *In general*—(1) *Scope.* This section provides rules for applying section 250 and §§ 1.250–1 through 1.250(b)–6 (the *section 250 regulations*) to a member of a consolidated group (*member*). Paragraph (b) of this section provides rules for the determination of the amount of the deduction allowed to a member under section 250(a)(1). Paragraph (c) of this section provides rules governing the impact of intercompany transactions on the determination of a member's qualified business asset investment (QBAI) and the effect of intercompany transactions on the determination of a member's foreign-derived deduction eligible income (FDDEI). Paragraph (d) of this section provides rules governing basis adjustments to member stock resulting from the application of paragraph (b)(1) of this section. Paragraph (e) of this section provides definitions. Paragraph (f) of this section provides examples illustrating the rules of this section. Paragraph (g) of this section provides an applicability date.

(2) *Overview.* The rules of this section ensure that the aggregate amount of deductions allowed under section 250 to members appropriately reflects the income, expenses, gains, losses, and property of all members. Paragraph (b) of this section allocates the consolidated group's overall deduction amount under section 250 to each member on the basis of its contribution to the consolidated foreign-derived deduction eligible income (consolidated FDDEI) and consolidated global intangible low-taxed income (consolidated GILTI). The definitions in paragraph (e) of this section provide for the aggregation of the deduction eligible income (DEI), FDDEI, deemed tangible income return, and global intangible low-taxed income (GILTI) of all members in order to calculate the consolidated group's overall deduction amount under section 250.

(b) *Allowance of deduction*—(1) *In general.* A member is allowed a deduction for a consolidated return year under section 250. See § 1.250(a)–1(b). The amount of the deduction is equal to the sum of—

(i) The product of the consolidated FDII deduction amount and the member's FDII deduction allocation ratio; and

(ii) The product of the consolidated GILTI deduction amount and the member's GILTI deduction allocation ratio.

(2) *Consolidated taxable income limitation.* For purposes of applying the limitation described in § 1.250(a)–1(b)(2) to the determination of the consolidated FDII deduction amount and the consolidated GILTI deduction amount of a consolidated group for a consolidated return year—

(i) The consolidated foreign-derived intangible income (consolidated FDII) (if any) is reduced (but not below zero) by an amount which bears the same ratio to the consolidated section 250(a)(2) amount that such consolidated FDII bears to the sum of the consolidated FDII and the consolidated GILTI; and

(ii) The consolidated GILTI (if any) is reduced (but not below zero) by the excess of the consolidated section 250(a)(2) amount over the reduction described in paragraph (b)(2)(i) of this section.

(c) *Impact of intercompany transactions*—(1) *Impact on qualified business asset investment determination*—(i) *In general.* For purposes of determining a member's QBAI, the basis of specified tangible property does not include an amount equal to any gain or loss recognized with respect to such property by another member in an intercompany transaction (as defined in § 1.1502–13(b)(1)) until the time that such gain or loss is no longer deferred under § 1.1502–13. Thus, for example, if a selling member owns specified tangible property with an adjusted basis (within the meaning of section 1011) of $60x and an adjusted basis (for purposes of calculating QBAI) of $80x, and sells it for $50x to the purchasing member (and the intercompany loss remains deferred), the basis of such property for purposes of computing the purchasing member's QBAI is $80x.

(ii) *Partner-specific QBAI basis.* A member's partner-specific QBAI basis (as defined in § 1.250(b)–2(g)(7)) includes a basis adjustment under section 743(b) resulting from an intercompany transaction only at the time, and to the extent, gain or loss, if any, is recognized in the transaction and no longer deferred under § 1.1502–13.

(2) *Impact on foreign-derived deduction eligible income characterization.* For purposes of redetermining attributes of members from an intercompany transaction as FDDEI, see § 1.1502–13(c)(1)(i) and (c)(7)(ii)(R) (*Example 18).*

(d) *Adjustments to the basis of a member.* For adjustments to the basis of a member related to paragraph (b)(1) of this section, see § 1.1502–32(b)(3)(ii)(B).

(e) *Definitions.* The following definitions apply for purposes of this section.

(1) *Consolidated deduction eligible income (consolidated DEI).* With respect to a consolidated group for a consolidated return year, the term *consolidated deduction eligible income* or *consolidated DEI* means the greater of the sum of the DEI (whether positive or negative) of all members or zero.

(2) *Consolidated deemed intangible income.* With respect to a consolidated group for a consolidated return year, the term *consolidated deemed intangible income* means the excess (if any) of the consolidated DEI, over the consolidated deemed tangible income return.

(3) *Consolidated deemed tangible income return.* With respect to a consolidated group for a consolidated return year, the term *consolidated deemed tangible income return* means the sum of the deemed tangible income return of all members.

(4) *Consolidated FDII deduction amount.* With respect to a consolidated group for a consolidated return year, the term *consolidated FDII deduction amount* means the product of the FDII deduction rate and the consolidated FDII, as adjusted by paragraph (b)(2) of this section.

(5) *Consolidated foreign-derived deduction eligible income (consolidated FDDEI).* With respect to a consolidated group for a consolidated return year, the term *consolidated foreign-derived deduction eligible income* or *consolidated FDDEI* means the greater of the sum of the FDDEI (whether positive or negative) of all members or zero.

(6) *Consolidated foreign-derived intangible income (consolidated FDII).* With respect to a consolidated group for a consolidated return year, the term *consolidated foreign-derived intangible income* or *consolidated FDII* means the product of the consolidated deemed intangible income and the consolidated foreign-derived ratio.

(7) *Consolidated foreign-derived ratio.* With respect to a consolidated group for a consolidated return year, the term *consolidated foreign-derived ratio* means the ratio (not to exceed one) of—

(i) The consolidated FDDEI; to

(ii) The consolidated DEI.

(8) *Consolidated GILTI deduction amount.* With respect to a consolidated group for a consolidated return year, the term *consolidated GILTI deduction amount* means the product of the GILTI deduction rate and the sum of the consolidated GILTI, as adjusted by paragraph (b)(2) of this section, and the amounts treated as dividends received by the members under section 78 which are attributable to their GILTI for the consolidated return year.

(9) *Consolidated global intangible low-taxed income (consolidated GILTI).* With respect to a consolidated group for a consolidated return year, the term *consolidated global intangible low-taxed income* or *consolidated GILTI* means the sum of the GILTI of all members.

(10) *Consolidated section 250(a)(2) amount.* With respect to a consolidated group for a consolidated return year, the term *consolidated section 250(a)(2) amount* means the excess (if any) of the sum of the consolidated FDII and the consolidated GILTI (determined without regard to section 250(a)(2) and paragraph (b)(2) of this section), over the consolidated taxable income of the consolidated group (within the meaning of § 1.1502–11).

(11) *Deduction eligible income (DEI).* With respect to a member for a consolidated return year, the term *deduction eligible income* or *DEI* means the member's gross DEI for the year (within the meaning of § 1.250(b)–1(c)(15)) reduced (including below zero) by the deductions properly allocable to gross DEI for the year (as determined under § 1.250(b)–1(d)(2)).

(12) *Deemed tangible income return.* With respect to a member for a consolidated return year, the term *deemed tangible income return* means an amount equal to 10 percent of the member's QBAI, as adjusted by paragraph (c)(1) of this section.

(13) *FDII deduction allocation ratio.* With respect to a member for a consolidated return year, the term *FDII deduction allocation ratio* means the ratio of—

(i) The member's positive FDDEI (if any); to

(ii) The sum of the positive FDDEI of all members.

(14) *FDII deduction rate.* The term *FDII deduction rate* means 37.5 percent for consolidated return years beginning before January 1, 2026, and 21.875 percent for consolidated return years beginning after December 31, 2025.

(15) *Foreign-derived deduction eligible income (FDDEI).* With respect to a member for a consolidated return year, the term *foreign-derived deduction eligible income* or *FDDEI* means the member's gross FDDEI for the year (within the meaning of § 1.250(b)–1(c)(16)) reduced (including below zero) by the deductions properly allocable to gross FDDEI for the year (as determined under § 1.250(b)–1(d)(2)).

(16) *GILTI deduction allocation ratio.* With respect to a member for a consolidated return year, the term *GILTI*

deduction allocation ratio means the ratio of—

(i) The sum of the member's GILTI and the amount treated as a dividend received by the member under section 78 which is attributable to its GILTI for the consolidated return year; to

(ii) The sum of consolidated GILTI and the amounts treated as dividends received by the members under section 78 which are attributable to their GILTI for the consolidated return year.

(17) *GILTI deduction rate.* The term *GILTI deduction rate* means 50 percent for consolidated return years beginning before January 1, 2026, and 37.5 percent for consolidated return years beginning after December 31, 2025.

(18) *Global intangible low-taxed income (GILTI).* With respect to a member for a consolidated return year, the term *global intangible low-taxed income* or *GILTI* means the sum of the member's GILTI inclusion amount under § 1.1502–51(b) and the member's distributive share of any domestic partnership's GILTI inclusion amount under § 1.951A–5(b)(2).

(19) *Qualified business asset investment (QBAI).* The term *qualified business asset investment* or *QBAI* has the meaning provided in § 1.250(b)–2(b).

(20) *Specified tangible property.* The term *specified tangible property* has the meaning provided in § 1.250(b)–2(c)(1).

(f) *Examples.* The following examples illustrate the rules of this section.

(1) *Example 1: Calculation of deduction attributable to FDII*—(i) *Facts.* P is the common parent of the P group and owns all of the only class of stock of subsidiaries USS1 and USS2. The consolidated return year of all persons is the calendar year. In 2018, P has DEI of $400x, FDDEI of $0, and QBAI of $0; USS1 has DEI of $200x, FDDEI of $200x, and QBAI of $600x; and USS2 has DEI of −$100x, FDDEI of $100x, and QBAI of $400x. The P group has consolidated taxable income that is sufficient to make inapplicable the limitation in paragraph (b)(2) of this section. No member of the P group has GILTI.

(ii) *Analysis*—(A) *Consolidated DEI.* Under paragraph (e)(1) of this section, the P group's consolidated DEI is $500x, the greater of the sum of the DEI (whether positive or negative) of all members ($400x + $200x − $100x) or zero.

(B) *Consolidated FDDEI.* Under paragraph (e)(5) of this section, the P group's consolidated FDDEI is $300x, the greater of the sum of the FDDEI (whether positive or negative) of all members ($0 + $200x + $100x) or zero.

(C) *Consolidated deemed tangible income return.* Under paragraph (e)(12) of this section, a member's deemed tangible income return is 10 percent of its QBAI. Therefore, P's deemed tangible income return is $0 (0.10 × $0), USS1's deemed tangible income return is $60x (0.10 × $600x), and USS2's deemed tangible income return is $40x (0.10 × $400x). Under paragraph (e)(3) of this section, the P group's consolidated deemed tangible income return is $100x, the sum of the deemed tangible income return of all members ($0 + $60x + $40x).

(D) *Consolidated deemed intangible income.* Under paragraph (e)(2) of this section, the P group's consolidated deemed intangible income is $400x, the excess of its consolidated DEI over its consolidated deemed tangible income return ($500x − $100x).

(E) *Consolidated FDII.* Under paragraph (e)(7) of this section, the P group's consolidated foreign-derived ratio is 0.60, the ratio of its consolidated FDDEI to its consolidated DEI ($300x/$500x). Under paragraph (e)(6) of this section, the P group's consolidated FDII is $240x, the product of its consolidated deemed intangible income and its consolidated foreign-derived ratio ($400x × 0.60).

(F) *Consolidated FDII deduction amount.* Under paragraph (e)(4) of this section, the P group's consolidated FDII deduction amount is $90x, the product of the FDII deduction rate and the consolidated FDII (0.375 × $240x).

(G) *Member's deduction attributable to consolidated FDII deduction amount.* Under paragraph (b)(1) of this section, a member is allowed a deduction equal, in part, to the product of the consolidated FDII deduction amount of the consolidated group to which the member belongs and the member's FDII deduction allocation ratio. Under paragraph (e)(13) of this section, a member's FDII deduction allocation ratio is the ratio of its positive FDDEI to the sum of each member's positive FDDEI for such consolidated return year. As a result, the FDII deduction allocation ratios of P, USS1, and USS2 are 0 ($0/$300x), ⅔ ($200x/$300x), and ⅓ ($100x/$300x), respectively. Therefore, P, USS1, and USS2 are permitted deductions under paragraph (b)(1) of this section in the amount of $0 (0 × $90x), $60x (⅔ × $90x), and $30x (⅓ × $90x), respectively.

(2) *Example 2: Limitation on consolidated foreign-derived deduction eligible income*—(i) *Facts.* The facts are the same as in paragraph (f)(1)(i) of this section (the facts in *Example 1*), except that P's FDDEI is $300x.

(ii) *Analysis*—(A) *Consolidated DEI and consolidated deemed tangible income return.* As in paragraphs (f)(1)(ii)(A) and (C) of this section (the analysis in *Example 1*), the P group's consolidated DEI is $500x and the P group's consolidated deemed tangible income return is $100x.

(B) *Consolidated FDDEI.* Under paragraph (e)(5) of this section, the P group's consolidated FDDEI is $600x, the greater of the sum of the FDDEI (whether positive or negative) of all members ($300x + $200x + $100x) or zero.

(C) *Consolidated deemed intangible income and consolidated FDII.* Under paragraph (e)(2) of this section, the P group's consolidated deemed intangible income is $400x ($500x − $100x). Under paragraph (e)(7) of this section, the P group's consolidated foreign-derived ratio is 1.00 ($600x/$500x, but not in excess of one). Under paragraph (e)(6) of this section, the P group's consolidated FDII is $400x ($400x × 1.00).

(D) *Consolidated FDII deduction amount and member's deduction attributable to consolidated FDII deduction amount.* Under paragraph (e)(4) of this section, the P group's consolidated FDII deduction amount is $150x (0.375 × $400x). Under paragraph (e)(13) of this section, the FDII deduction allocation ratios of P, USS1, and USS2 are ½ ($300/$600x), ⅓ ($200x/$600x), and ⅙ ($100x/$600x), respectively. Therefore, P, USS1, and USS2 are permitted deductions under paragraph (b)(1) of this section in the amounts of $75x (½ × $150x), $50x (⅓ × $150x), and $25x (⅙ × $150x), respectively.

(3) *Example 3: Member with negative FDDEI*—(i) *Facts.* The facts are the same as in paragraph (f)(1)(i) of this section (the facts in *Example 1*), except that P's FDDEI is -$100x.

(ii) *Analysis*—(A) *Consolidated DEI and consolidated deemed tangible income return.* As in paragraphs (f)(1)(ii)(A) and (C) of this section (the facts in *Example 1*), the P group's consolidated DEI is $500x and the P group's consolidated deemed tangible income return is $100x.

(B) *Consolidated FDDEI.* Under paragraph (e)(5) of this section, the P group's consolidated FDDEI is $200x, the greater of the sum of the FDDEI (whether positive or negative) of all members (−$100x + $200x + $100x) or zero.

(C) *Consolidated deemed intangible income and consolidated FDII.* Under paragraphs (e)(2) and (6) of this section, the P group's consolidated deemed intangible income is $400x ($500x −$100x), and the P group's consolidated FDII is $160x ($400x × ($200x/$500x)).

(D) *Consolidated FDII deduction amount and member's deduction attributable to consolidated FDII deduction amount.* Under paragraph (e)(4) of this section, the P group's consolidated FDII deduction amount is $60x (0.375 × $160x). Under paragraph (e)(13) of this section, the FDII deduction allocation ratios of P, USS1, and USS2 are 0 ($0/$300x), ⅔ ($200x/$300x), and ⅓ ($100x/$300x), respectively. Therefore, P, USS1, and USS2 are permitted deductions under paragraph (b)(1) of this section in the amounts of $0 (0 × $60x), $40x (⅔ × $60x), and $20x (⅓ × $60x), respectively.

(4) *Example 4: Calculation of deduction attributable to GILTI*—(i) *Facts.* The facts are the same as in paragraph (f)(1)(i) of this section (the facts in *Example 1*), except that USS1 owns CFC1 and USS2 owns CFC2. USS1 and USS2 have GILTI of $65x and $20x, respectively, and amounts treated as dividends received under section 78 attributable to their GILTI of $10x and $5x, respectively.

(ii) *Analysis*—(A) *Consolidated GILTI.* Under paragraph (e)(9) of this section, the P group's consolidated GILTI is $85x, the sum of the GILTI of all members ($0 + $65x + $20x).

(B) *Consolidated GILTI deduction amount.* Under paragraph (e)(8) of this section, the P group's consolidated GILTI deduction amount is $50x, the product of the GILTI deduction rate and the sum of its consolidated GILTI and the amounts treated as dividends received by the members under section 78 which are attributable to their

GILTI for the consolidated return year (0.50 × ($85x + $10x + $5x)).

(C) *Member's deduction attributable to consolidated GILTI deduction amount.* Under paragraph (b)(1) of this section, a member is allowed a deduction equal, in part, to the product of the consolidated GILTI deduction amount of the consolidated group to which the member belongs and the member's GILTI deduction allocation ratio. Under paragraph (e)(16) of this section, a member's GILTI deduction allocation ratio is the ratio of the sum of its GILTI and the amount treated as a dividend received by the member under section 78 which is attributable to its GILTI for the consolidated return year to the sum of the consolidated GILTI and the amounts treated as dividends received by the members under section 78 which are attributable to their GILTI for the consolidated return year. As a result, the GILTI deduction allocation ratios of P, USS1, and USS2 are 0 ($0/($85x + $10x + $5x)), ¾ (($65x + $10x)/($85x + $10x + $5x)), and ¼ (($20x + $5x)/($85x + $10x + $5x)), respectively. Therefore, P, USS1, and USS2 are permitted deductions of $0 (0 × $50x), $37.50x (¾ × $50x), and $12.50x (¼ × $50x), respectively.

(D) *Member's deduction under section 250.* Under paragraph (b)(1) of this section, a member is allowed a deduction equal to the sum of the member's deduction attributable to the consolidated FDII deduction amount and the member's deduction attributable to the consolidated GILTI deduction amount. As a result P, USS1, and USS2 are entitled to deductions under paragraph (b)(1) of this section of $0 ($0 + $0), $97.50x ($60x + $37.50x), and $42.50x ($30x + $12.50x), respectively.

(5) *Example 5: Taxable income limitation*—(i) *Facts.* The facts are the same as in paragraph (f)(4)(i) of this section (the facts in *Example 4*), except that the P group's consolidated taxable income (within the meaning of paragraph (e)(10) of this section) is $300x.

(ii) *Analysis*—(A) *Determination of whether the limitation described in paragraph (b)(2) of this section applies.* Under paragraph (b)(2) of this section, in the case of a consolidated group with a consolidated section 250(a)(2) amount for a consolidated year, the amount of the consolidated FDII and the consolidated GILTI otherwise taken into account in the determination of the consolidated FDII deduction amount and the consolidated GILTI deduction amount are subject to reduction. As in paragraph (f)(1)(ii)(E) of this section (the facts in *Example 1*), the P group's consolidated FDII is $240x. As in paragraph (f)(4)(ii)(A) of this section (the analysis in *Example 4*), the P group's consolidated GILTI is $85x. The P group's consolidated taxable income is $300x. Under paragraph (e)(10) of this section, the P group's consolidated section 250(a)(2) amount is $25x (($240x + $85x) − $300x), the excess of the sum of the consolidated FDII and the consolidated GILTI, over the P group's consolidated taxable income. Therefore, the limitation described in paragraph (b)(2) of this section applies.

(B) *Allocation of reduction.* Under paragraph (b)(2)(i) of this section, the P group's consolidated FDII is reduced by an amount which bears the same ratio to the consolidated section 250(a)(2) amount as the consolidated FDII bears to the sum of the consolidated FDII and consolidated GILTI, and the P group's consolidated GILTI is reduced by the excess of the consolidated section 250(a)(2) amount over the reduction described in paragraph (b)(2)(i) of this section. Therefore, for purposes of determining the P group's consolidated FDII deduction amount and consolidated GILTI deduction amount, its consolidated FDII is reduced to $221.54x ($240x − ($25x × ($240x/$325x))) and its consolidated GILTI is reduced to $78.46x ($85x − ($25x − ($25x × ($240x/$325x)))).

(C) *Calculation of consolidated FDII deduction amount and consolidated GILTI deduction amount.* Under paragraph (e)(4) of this section, the P group's consolidated FDII deduction amount is $83.08x ($221.54x × 0.375). Under paragraph (e)(8) of this section, the P group's consolidated GILTI deduction amount is $46.73x (($78.46x + 10x + 5x) × 0.50).

(D) *Member's deduction attributable to the consolidated FDII deduction amount.* As in paragraph (f)(1)(ii)(G) of this section (the analysis in *Example 1*), the FDII deduction allocation ratios of P, USS1, and USS2 are 0, ⅔, and ⅓, respectively. Therefore, P, USS1, and USS2 are permitted deductions attributable to the consolidated FDII deduction amount of $0 (0 × $83.08x), $55.39x (⅔ × $83.08x), and $27.69x (⅓ × $83.08x), respectively.

(E) *Member's deduction attributable to the consolidated GILTI deduction amount.* As in paragraph (f)(4)(ii)(C) of this section (the analysis in *Example 4*), the GILTI deduction allocation ratios of P, USS1, and USS2 are 0, ¾, and ¼, respectively. Therefore, P, USS1, and USS2 are permitted deductions attributable to the consolidated GILTI deduction amount of $0 (0 × $46.73x), $35.05x (¾ × $46.73x), and $11.68x (¼ × $46.73x), respectively.

(F) *Member's deduction pursuant section 250.* Under paragraph (b)(1) of this section, a member is allowed a deduction equal to the sum of the member's deduction attributable to the consolidated FDII deduction amount and the member's deduction attributable to the consolidated GILTI deduction amount. As a result, P, USS1, and USS2 are entitled to deductions under paragraph (b)(1) of this section of $0 ($0 + $0), $90.44x ($55.39x + $35.05x), and $39.37 × ($27.69x + $11.68x), respectively.

(g) *Applicability date.* This section applies to consolidated return years beginning on or after January 1, 2021. A taxpayer that chooses to apply the rules in §§ 1.250(a)–1 and 1.250(b)–1 through 1.250(b)–6 to taxable years beginning before January 1, 2021, pursuant to § 1.250–1(b), must also apply the rules of this section in their entirety to consolidated return years beginning after December 31, 2017, and before January 1, 2021.

■ **Par. 8.** Section 1.6038–2 is amended by adding paragraphs (f)(15) and (m)(4) to read as follows:

§ 1.6038–2 Information returns required of United States persons with respect to annual accounting periods of certain foreign corporations.

* * * * *

(f) * * *

(15) *Information reporting under section 250.* If the person required to file Form 5471 (or any successor form) claims a deduction under section 250(a) that is determined, in whole or part, by reference to its foreign-derived intangible income, and any amount required to be reported under paragraph (f)(11) of this section is included in its computation of foreign-derived deduction eligible income, such person will provide on Form 5471 (or any successor form) such information that is prescribed by the form, instructions to the form, publication, or other guidance published in the Internal Revenue Bulletin.

* * * * *

(m) * * *

(4) Paragraph (f)(15) of this section applies with respect to information for annual accounting periods beginning on or after March 4, 2019.

■ **Par. 9.** Section 1.6038–3 is amended by adding paragraph (g)(4) and a sentence to the end of paragraph (l) to read as follows:

§ 1.6038–3 Information returns required of certain United States persons with respect to controlled foreign partnerships (CFPs).

* * * * *

(g) * * *

(4) *Additional information required to be submitted by a controlling ten-percent or a controlling fifty-percent partner that has a deduction under section 250 by reason of FDII.* In addition to the information required pursuant to paragraphs (g)(1), (2), and (3) of this section, if, with respect to the partnership's tax year for which the Form 8865 is being filed, a controlling ten-percent partner or a controlling fifty-percent partner has a deduction under section 250 (by reason of having foreign-derived intangible income), determined, in whole or in part, by reference to the income, assets, or activities of the partnership, or transactions between the controlling-ten percent partner or controlling fifty-percent partner and the partnership, the controlling ten-percent partner or controlling fifty-percent partner must provide its share of the partnership's gross DEI, gross FDDEI, deductions that are properly allocable to the partnership's gross DEI and gross FDDEI, and partnership QBAI (as those terms are defined in the section 250 regulations) in the form and manner and to the extent prescribed by Form 8865 (or any successor form), instructions to

the form, publication, or other guidance published in the Internal Revenue Bulletin. To the extent that the partnership amounts described in the previous sentence cannot be determined, the controlling ten-percent partner or controlling fifty-percent partner must provide its share of the partnership's attributes that the partner uses to determine the partner's gross DEI, gross FDDEI, deductions that are properly allocable to the partner's gross DEI and gross FDDEI, and the partner's adjusted bases in partnership specified tangible property.

* * * * *

(l) * * * Paragraph (g)(4) of this section applies for tax years of a foreign partnership beginning on or after March 4, 2019.

■ **Par. 10.** Section 1.6038A–2 is amended by adding paragraph (b)(5)(iv) and a sentence at the end of paragraph (g) to read as follows:

§ 1.6038A–2 Requirement of return.

* * * * *

(b) * * *

(5) * * *

(iv) If, for the taxable year, the reporting corporation has a deduction under section 250 (by reason of having foreign-derived intangible income) with respect to any amount required to be reported under paragraph (b)(3) or (4) of this section, the reporting corporation will provide on Form 5472 (or any successor form) such information about the deduction in the form and manner and to the extent prescribed by Form 5472 (or any successor form), instructions to the form, publication, or other guidance published in the Internal Revenue Bulletin.

* * * * *

(g) * * * Paragraph (b)(5)(iv) of this section applies with respect to information for annual accounting periods beginning on or after March 4, 2019.

Douglas W. O'Donnell,

Acting Deputy Commissioner for Services and Enforcement.

Approved: June 12, 2020.

David J. Kautter

Assistant Secretary of the Treasury (Tax Policy).

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